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ALTERNATIVE REIMBURSEMENT APPROACHES FOR HEARING AIDS AND IMPLICATIONS FOR MEDICAID POLICY

Medical Services Administration
Social and Rehabilitation Service
U.S. Department of Health, Education
and Welfare

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1. *SUMMARY OF CONCLUSIONS AND RECOMMENDATIONS*

This study examines the hearing aid reimbursement policies of five Medicaid programs - California, Connecticut, Michigan, New Jersey, and Washington. The study also reviews various other programs reimbursing for hearing aids, especially the Veterans Administration. Complete information on all these programs may be found in Section 3. In addition, this paper outlines the structures and relationships of the hearing aid industry as well as the roles and functions of physicians and audiologists. This was done to define the environment in which Medicaid hearing aid reimbursement takes place. This information on the industry and hearing professionals may be found in Section 2.

Based on the review both of the methods of reimbursement, the hearing aid industry and professional activities the following was found:

- The retail price of a hearing aid is two to three times the wholesale cost of the aid to hearing aid dealers.
- Medicaid reimbursement policies for hearing aids do not in many cases differentiate costs of equipment and dealer services, hindering rational and prudent cost limits.
- Medicaid reimbursements do not reflect actual services rendered by dealers to Medicaid recipients, but allow additional and extraneous charges.
- The quality of hearing aids is open to serious question and Medicaid has no effective means of assuring quality.

- Hearing aids in Medicaid should be dispensed only after otological or audiological exams, but these exams are not always given.

Given these findings, the following recommendations are suggested for Medicaid reimbursement for hearing aids:

- In all cases, Medicaid programs should differentiate dealers' fees from equipment costs.
- Fixed dealers' fees should be established to reflect only those services necessary to provide a hearing aid to a Medicaid recipient.
- State Medicaid programs should specifically define approved hearing aids for reimbursement based on the VA study of hearing aid quality and cost effectiveness.
- Maximum prices for approved aids should be set at manufacturers' selling prices to the dealer.
- Medicaid policy on the examinations necessary before a hearing aid is dispensed should be made explicit and include clearly defined procedures for both medical and audiological examinations.
- Specific procedures codes should be implemented for professional services related to testing for hearing aids.

2. *BACKGROUND*

2.1 *BASIC HEARING AID STATISTICS*

The American Speech and Hearing Association estimates that approximately 500,000 hearing aids are sold each year in the United States. At an average retail cost of about $350.00, this suggests a current annual retail expenditure of around $180 million for hearing aids. This compares with total sales of $132 million in 1973.

Table 1 shows typical total professional services and device costs associated with obtaining a hearing aid. As can be seen, this cost of the device represents 75-85% of the total costs. The costs noted in Table 1 do not include such miscellaneous costs as batteries, repairs, rentals, and other items. These costs represent about 25% of a hearing aid dealer's sales, according to a 1972 California survey.

Table 2 summarizes estimated annual expenditures for hearing aids by source of cost. The $58 million estimated for professional services is probably overstated but is included to suggest a general magnitude. According to various sources, however, between 60% and 70% of hearing aids are purchased without professional involvement. In some of these cases, the hearing aid dealer may provide test services.

In 1975, the National Hearing Aid Society (NHAS) estimated that about 3.5 million hearing aids were in use, over half of which were used by those aged 65 and over. The NHAS also noted that this represents a doubling of hearing aid wearers since 1971.

Compared to other health care services and products, hearing aids are a relatively minor cost item. In fact, in 1975, the personal health care

Table 1

TYPICAL COST FACTORS ASSOCIATED WITH
ACQUISITION OF ONE HEARING AID

Medical Examination[a]		$ 35 - 60
Hearing Test[b]		30 - 50
Device Costs		365
Device[c]	$130	
Dealer Fee[d]	235	
Total		$430 - 475

[a]based on initial intermediate office visit (CRVS 90015) for otologist or otolaryngologist, and current California Medi-Cal conversion factor

[b]based on California Medi-Cal maximum allowance for diagnostic audiological evaluation (0801)

[c]based on average unit wholesale cost for device and accessories, 1971 Michigan study

[d]1.8 times device wholesale cost, based on 1972 California report on hearing aid dealer operating expenses

Table 2

ESTIMATED TOTAL NATIONAL EXPENDITURES FOR
HEARING AIDS AND RELATED SERVICES (millions)

Professional Services[a]		$ 58
Hearing Aid Dealers		230
Hearing Aids	$175	
Accessories[b]	34	
Repairs (parts and labor)	16	
Other (rentals and other)	5	
Total		$288

[a]medical and hearing evaluation examinations by otologist, otolaryngologist, or other physicians, and audiologists

[b]ear molds, batteries, tubes and cords; audiologists can also supply batteries

expenditures for hearing aids, $180 million, represented less than two-tenths of one percent (.2%) of such expenditures. Table 3 gives a breakdown of expenditures for major health services.

Table 3

PERSONAL HEALTH CARE EXPENDITURES
BY SERVICE AND AMOUNT (1975)

Service	Amount (billions)
Hospital	$ 46.6
Physician	22.1
Drugs	10.6
Nursing Homes	9.0
Dentists	7.5
Other Health Services	3.0
Other Professional Services	2.1
Eyeglasses	1.9
Other Appliances	.22
Hearing Aids	.18
Total	$103.2

These figures listed specifically for hearing aids do not include the costs of medical and audiological examinations.

Over 95% of payments for hearing aids come from private sources, mostly out-of-pocket sources. Medicare does not cover hearing aids or hearing examinations. Very few private health insurance policies provide any coverage of hearing aid costs. Medicaid does cover hearing aids for children through the EPSDT program, and 25 state Medicaid programs cover hearing aids for adults. Total expenditures in Medicaid for hearing examinations and devices are not available because the reporting of such expenditures is lumped with several additional services in an "other" category.

Not counting Medicaid, the public monies spent for hearing aids are primarily in Workmen's Compensation, the Veterans Administration, and several other programs. The approximate percentage of public expenditures each of these programs represents is presented in Table 3.

Table 4

PERCENTAGE OF PUBLIC EXPENDITURES
FOR HEARING AIDS BY PROGRAM (1975)

Workmen's Compensation	36.0
Veterans Administration	30.0
Vocational Rehabilitation	17.6
Maternal and Child Health	13.7
Other	0.7
Total	98.0% *

Source: "National Health Care Expenditures", Social Security Bulletin, February 1976.

*Figures do not total 100 due to rounding.

2.2 *PROCESS OF OBTAINING HEARING CARE*

This section presents information on the extent and kinds of hearing problems in the U.S. population and the various means available for correcting these problems. In addition, the industry which supplies hearing aids to the American public is discussed.

2.2.1 *CONSUMERS: HEARING PROBLEMS AND HEARING AIDS*

Currently, about 14.5 million Americans are estimated by the HEW Task Force on Hearing Aids as having some form of hearing impairment. Of this number, about 10 million have received no medical attention for their problems.

Hearing problems are of several kinds. A description of each follows:

- Conductive: Conductive loss of hearing is caused by a failure in some part of the physical linkage of tissues and bones that conduct sounds from the eardrum to the nerve centers of the inner ear. Conductive hearing loss is usually associated with wax build-up or damage to the ear drum. The actual hearing loss is something like a uniform blockage or muffling of sound. In general, conductive hearing loss is best treated by drugs or surgery. Conductive hearing loss is found in approximately 5% of those with a hearing impairment.

- Sensorineural: Sensorineural hearing loss comes from damage to or malfunction of the nerve centers in the inner ear, the nerve pathways to the brain, or to that portion of the brain which receives the audio nerve impulses. This form of hearing loss can be caused by birth defects, illnesses, drugs, head injuries, and most commonly, exposure to noise and aging (called presbycusis). Sensorineural hearing loss is not uniform and affects only certain sound frequencies or tones. Treatment for sensorineural hearing loss generally requires a hearing aid. Sensorineural hearing loss affects approximately 95% of those with hearing impairments.

- Mixed: This kind of hearing impairment occurs when both conductive and sensorineural hearing dysfunctions can be found in combination.

Without becoming too technical, it is helpful to understand how hearing loss is measured. The basic unit of sound measurement is the decibel (dB). A decibel may be defined as follows:

> One decibel is the least intensity of sound at which any given note can be heard. A scale of decibels is a logarithmic construct that indicates the intensity of sound above one decibel. The more decibels, the stronger the sound.

In measuring hearing there are two thresholds: the threshold of hearing, the weakest sound one can hear; and the threshold of discomfort, the loudest sound one can hear without pain. The normal range for hearing is from near 0 dB to 120 dB.

In testing for hearing loss, the important measure is the weakest sound (in decibels) that can be heard. Table 5 describes levels of hearing loss

in terms of decibels, how the loss is characterized, and their effects on an individual's hearing capacity.

Table 5

AMOUNT OF HEARING LOSS, CHARACTERIZATION AND EFFECTS

Lowest Threshold of Hearing (dB)	Characterization	Effect
0-15 (in the poorer ear)	Normal	No difficulties
15-30 (in the better ear)	Near normal	Difficulty with faint speech
30-45 (in the better ear)	Mild impairment	Difficulty with normal speech
45-60 (in the better ear)	Moderate impairment	Difficulty with loud speech
60-90 (in the better ear)	Severe impairment	Can understand only amplified speech
90 or more (in the better ear)	Profound impairment	Difficulty even with amplified speech

Source: "How to Buy a Hearing Aid, Part 1, What Consumers Should Know", Consumers Report, June, 1976, p. 548.

It is estimated that over one-half of all persons over the age of 65 have some form of hearing impairment. The most recent National Health Survey (1971) suggests that about half of the total hearing impaired population have good hearing in one ear and can function normally. The problems of hearing become more acute with bilateral (or both ears) hearing problems; people with bilateral hearing problems are most likely to need hearing aids. Table 6 describes the population with bilateral hearing impairments.

Table 6

PERSONS WITH BILATERAL HEARING
PROBLEMS BY DEGREE OF DIFFICULTY

Problem (Based on ability to hear without hearing aid)	Numbers (1,000s)	% of Total
Some difficulty hearing but can hear words spoken in a normal voice	4,210	60.5%
Can hear words shouted across room	1,886	27.1
Able to hear some words shouted in better ear	404	5.8
Unable to hear spoken words	362	5.2
Undetermined	97	1.4
Total	6,959	100.0%

Source: Persons with Impaired Hearing, United States, 1971, National Center for Health Statistics, November, 1975. Based on 1971 percentages applied to 1975 total estimate of bilaterally impaired.

Of those people who wear hearing aids, 60% are aged 65 or over. The distribution of hearing aid wearers for all age groups in 1971 is shown in Table 7.

As noted earlier, the current number of people wearing hearing aids is estimated by NHAS at 3.5 million, double the number in 1971. The important point, however, is that between 10 and 11 million people in need of hearing aids do not receive care. This situation has major implications. People with hearing impairments often suffer from related problems. Hearing impaired children may be mistakenly considered as slow-witted or as having behavioral problems. Adults face barriers to social and professional

Table 7

DISTRIBUTION OF PERSONS WEARING
HEARING AIDS BY AGE (1971)

Age	Hearing Aids (1,000s)	% of Total Population Wearing Hearing Aids
3-16	87	5.1%
17-24	46*	2.7*
25-44	91	5.4
45-64	436	25.7
65 & over	1,035	61.0
Total	1,695	99.9**

* statistically unreliable sample in this subgroup.

** does not total due to rounding

Source: Persons with Impaired Hearing, 1971, NCHS.

acceptance because of increased difficulty in communication. The elderly can be incorrectly considered senile because they cannot hear well. All age groups with hearing impairments are in danger of physical harm because they cannot hear alarms well. Moreover, many persons with hearing impairments also suffer from other handicaps. For example, many children with hearing defects also have speech impairments. Based on a study by the National Center for Health Statistics, Dr. Edward E. Perrin, NCHS Director, presented a composite demographic picture of hearing impaired persons:

> "Briefly, some of the specific findings...were that the prevalence of hearing impairment rose with age. It was higher for males than for females, and it was higher for white persons than for persons of other races. As family income rose, the prevalence of hearing impairments declines. A similar pattern was present with regard to education. The prevalence was considerably higher among persons living outside metropolitan areas than among those living in standard metropolitan statistical areas and it was lower among residents of the northeast region, than for persons residing elsewhere." [1]

[1] Testimony by Dr. Edward Perrin, NCHS Director, before the Senate Subcommittee on Small Businesses.

With reference to the emphasized information above, it should be noted that professional hearing services such as ear doctors and speech and hearing centers are located primarily in urban areas. This accounts for the large reliance on hearing aid dealers in rural areas, discussed later in this section.

2.2.2 *HEARING AIDS*

A hearing aid is a miniature amplifying system designed to make sounds louder. Practically all hearing aids are air conduction models, placing sounds in the ear canal through the ear piece. There are also bone conduction models which reverberate sound against the skull. These are very limited in their use.

Most hearing aids of the air-conduction type have five basic components. These are described in Table 8.

Table 8

HEARING AIDS BY COMPONENT AND FUNCTION

Component	Function
1. Microphone	Picks up sound waves and converts them into electrical signals
2. Amplifier	Increases the strengh of the signal
3. Battery	Provides energy
4. Receiver	Changes the electrical signal back to sound waves
5. Ear mold	Connects receiver to ear canal

Source: "Facts about Hearing Aids", Better Business Bureau, Consumer Information Series, p. 5.

There are four basic kinds of hearing aids, distinguished by their location on the body. The four kinds of hearing aids and selected characteristics are as follows.

Table 9

TYPES OF HEARING AIDS AND SELECTED CHARACTERISTICS

Type of Aid	Average Cost	Percent of Total Annual Sales	Type of Hearing Loss Best Suited For
In the Ear	$350.00	15.3%	Mild only (30-40 dB)*
On Eyeglasses	300.00	16.5	Mild to severe (30 to 90 dB)
Behind the Ear	300.00	65.9	Mild to severe (30 to 90 dB)
On the Body	250.00	5.6	Severe to profound (60 to 90 or more dB)

* Number of decibels at lowest threshold of hearing, see Table 5.

Source: Information provided by the Hearing Aid Industry Conference, the trade association of hearing aid manufacturers.

As indicated by the far right column in Table 9, the type of hearing aid depends on the magnitude of the hearing loss. A small in-the-ear aid has only enough power to provide amplification for mild hearing loss. Larger sets, such as behind-the-ear models and those attached to eyeglasses, are required for greated amplification. For serious hearing impairment, only the largest and most powerful on-the-body aids will suffice.

There are also special models of hearing aids designed for specific kinds of hearing loss. These include:

- Compression Models - In these aids strong sounds are amplified less than weak sounds.
- Directional Models - These models amplify sounds from the front more than the back, helping the wearer tell sound direction and identify background noise.
- High Frequency Emphasis Models - These aids specifically amplify treble.
- CROS Models - In these aids, the microphone is placed on the side opposite the dysfunctional ear, helping reduce background noise.
- BICROS Models - In this case, a microphone is placed on both sides of the head and signals are delivered to one ear, benefiting those with unequal amounts of impairment in each ear.

The price and quality of individual hearing aids will be discussed fully at the end of this section. Next will be discussed how a hearing aid is obtained.

2.2.3 *OBTAINING HEARING CARE AND HEARING AIDS*

Hearing care services are available from three sources:

- Otolaryngologists and Otologists - An otolaryngologist is a physician who specializes in the ear, nose, and throat. An otologist is a physician who specializes only in the ear. (For purposes of this study, otologist will be used to cover both specialities.) The primary responsibility of the otologist is the diagnosis and treatment of diseases of the auditory system. It is he or she who evaluates any hearing dysfunctions in terms of the overall medical condition of the patient. There are approximately 5,100 otologists in the United States.

- Audiologists - Clinical audiologists are generally university trained hearing specialists. The American Speech and Hearing Association (ASHA) has established minimum qualifications for audiologists. These are: An M.A. or equivalent in audiology including 300 hours or supervised clinical experience and 60 hours of course work; a one year internship in audiology; and passing a national examination in audiology. The audiologist performs and analyzes hearing tests to determine the need for and, if necessary, the type of hearing aid. The audiologist also may provide guidance, counseling and other services for those with impaired hearing. The ASHA says that it has certified 2,900 clinical audiologists and has 800 more now in training. The total number of audiologists in the country is 4,327 according to the ASHA.
- Hearing Aid Dealers - The hearing aid dealer sells and fits hearing aids and also supplies repair services for the devices. In general, hearing aid dealers refer to themselves as hearing aid specialists. There are approximately 7,750 hearing aid dealerships in this country with a total of over 15,000 dealers and salesmen. Of this 15,000, 2,200 have received a special 20-week home study course leading to certification by their association, the National Hearing Aid Society.

Table 10 presents a state-by-state distribution of otologists, audiologists, and hearing aid dealers.

According to the Retired Professional Action Group study, "Paying Through the Ear: A Report on Hearing Health Care Problems", over 70% of all persons with hearing aids obtained them directly from hearing aid

Table 10

OTOLOGISTS, AUDIOLOGISTS AND
HEARING AID DEALERS, BY STATE

	O[a] (1974)	A[b] (1976)	D[c] (1975)
United States	5077	4327	7753
Alabama	71	53	95
Alaska	6	11	n.a.
Arizona	49	45	92
Arkansas	33	24	84
California	652	468	761
Colorado	72	89	74[e]
Connecticut	99	62	171
Delaware	8	10	19
D.C.	35	36	18[e]
Florida	222	139	391
Georgia	84	63	93
Hawaii	26	15	n.a.
Idaho	11	10	58
Illinois	230	236	281[e]
Indiana	91	88	237
Iowa	55	98	142
Kansas	41	52	101
Kentucky	48	49	225
Louisiana	111	72	98
Maine	23	16	67
Maryland	128	157	140
Massachusetts	176	147	275
Michigan	161	156	306
Minnesota	88	66	90[e]
Mississippi	42	32	44
Missouri	123	79	272
Montana	18	31	23
Nebraska	34	39	82
Nevada	13	10	20
New Hampshire	18	8	25[e]
New Jersey	164	129	126
New Mexico	20	27	43
New York	573	457	405[e]
North Carolina	101	71	203
North Dakota	14	14	29
Ohio	227	213	564
Oklahoma	47	41	118
Oregon	63	48	175
Pennsylvania	310	221	575[e]
Rhode Island	30	21	58
South Carolina	42	36	92
South Dakota	7	13	27
Tennessee	95	102	137
Texas	258	207	434
Utah	31	43	24[e]
Vermont	8	8	25[e]
Virginia	110	96	133
Washington	88	97	142
West Virginia	32	30	71
Wisconsin	84	85[e]	188
Wyoming	5	7	14

[a] see year 1974; "Health Resources Statistics - 1974", National Center for Health Statistics, DHEW

[b] as of May, 1976; includes members of American Speech and Hearing Association only

[c] information from National Hearing Aid Society

e = estimated
n.a. = not available
O = Otolaryngologists
A = Audiologists
D = Hearing Aid Dealers

dealers, without consultation from an otologist or audiologist. The remaining 30% received their hearing aids after consultation with either an audiologist or otologist or both.

Most sources, including various professional and consumer associations, suggest that the following process should be followed to obtain a hearing aid:

- First, the consumer would visit an otologist for a physical examination and a determination of any specific pathology causing the hearing impairment. If a conductive impairment is determined, the patient will be treated by the otologist. If a sensorineural hearing loss is determined, the otologist will refer the patient to an audiologist for further testing or to a hearing aid dealer.

- Second, the patient goes to either an audiologist, many of whom work out of some 1,140 Speech and Hearing Centers or to a hearing aid dealer. The audiologist or the hearing aid dealer tests the patient to determine the magnitude of the hearing loss. Usually if there is a hearing loss of at least 50 dB, a hearing aid will be prescribed.

- Third, an audiologist may dispense the hearing aid or refer the patient to a hearing aid dealer who fills the prescription written by the audiologist. In the case of a hearing aid dealer doing the testing, she will supply the hearing aid directly. Normally hearing aids are not kept in stock, but must be ordered from the manufacturer. Some dealers do maintain small stocks. Both audiologists and dealers can fit ear molds, which are needed with nearly all hearing aids.

- Fourth, a follow-up examination of this patient is recommended to make sure the device is operating properly and to reinforce the patient's use of the aid. Such follow-ups can be performed by the otologist, the audiologist, the dealer, or a combination of these.

The FDA, in its hearing aid regulations of February 15, 1977, requires that the medical examination discussed above must be performed prior to purchase of a hearing aid, although this may be waived by those over

seventeen. Further discussion of the new FDA regulations may be found in Section 2.2.5.

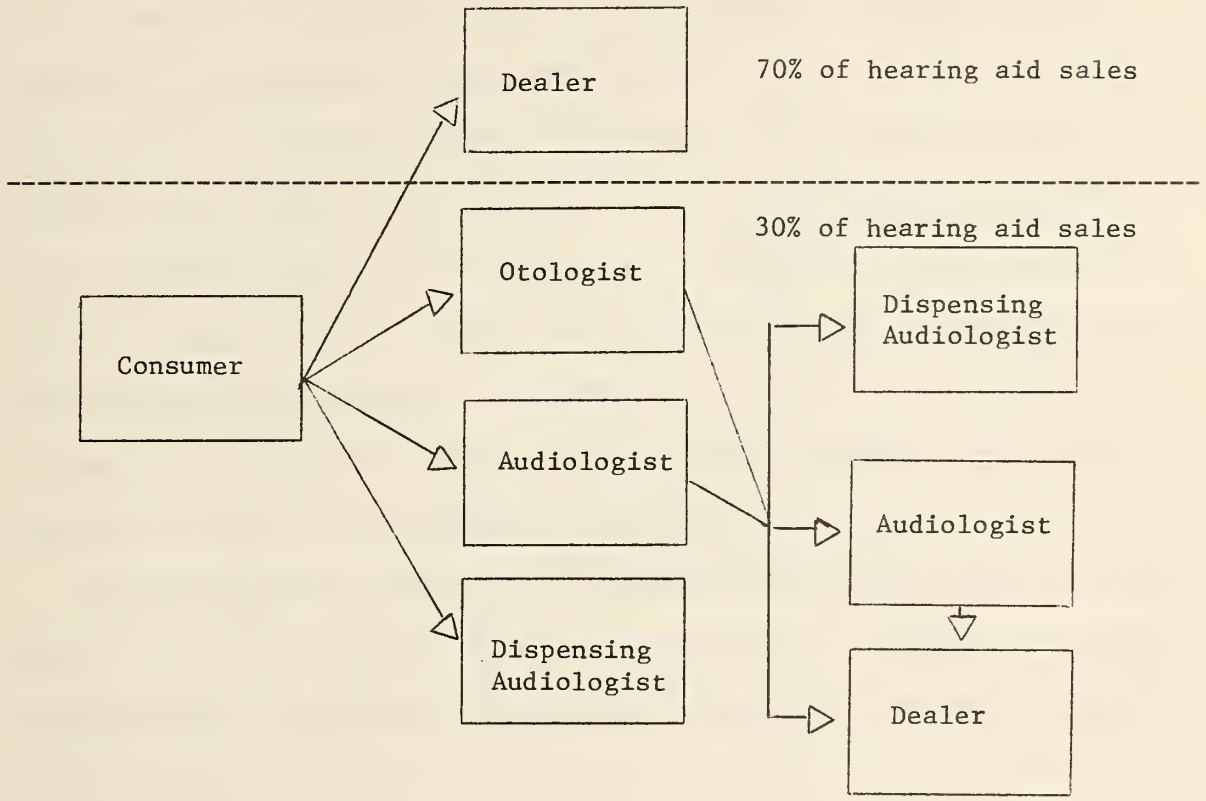
This recommended process has several advantages. It assures that the patient needs a hearing aid rather than some other medical treatment. It assures that the patient is accurately tested for a hearing aid. And it helps assure, by going through the whole process, that the patient will use the aid once he or she has it. There is one important drawback; all the steps in the process cost money. The average professional and dealer costs associated with the acquisition of a hearing aid are shown below:

. Otologist Exam	$ 30.00
. Audiologist Exam	35.00
. Hearing Aid Dealer Fee	150.00
Total	$ 215.00

Although the recommended process of obtaining a hearing aid has been discussed, there are numerous other options available in acquiring a hearing aid. These are presented in Figure 1. It should be noted that all visits in this process may not entail separate charges.

Figure 1

ALTERNATIVE METHODS OF OBTAINING A HEARING AID



2.2.4 *MANUFACTURERS*

Hearing aid dealers and dispensing audiologists normally receive their aids directly from the manufacturer. There are few hearing aid wholesalers except in the case of American firms who distribute foreign aids.

There are about 50 separate companies marketing hearing aids in the United States who make some 500 different hearing aid models. This figure includes both American hearing aid manufacturers and distributors of foreign made models. Of this total, four companies -- Beltone, Zenith, Dahlberg, and Qualitone -- controlled over 50 percent of the dollar value of shipments in the market in 1970, with Beltone alone capturing about 20 percent of this market. These firms, along with four other companies -- Maico, Audiotone, Sonotone, and Electone -- controlled over 70 percent of the sales volume, leaving only 30 percent of the market to be divided among the 40-odd smaller companies. According to calculations of the Retired Professionals Action Group (RPAG), the top eight companies sold 424,779 hearing aids, while the remaining 42 sold 182,048 in 1972.

Between the years 1970 and 1975, domestic sales rose about 23 percent. However, imports have increased about 46 percent -- or double the rate for domestic sales -- and account for nearly one-fourth of the total sales as can be seen in Table 11. .

The number of hearing aids sold, as can be seen from the various estimates this paper has presented, is very much open to question. Initially, it was suggested that 500,000 hearing aids were sold in the United States in 1975. The Retired Professionals Action Group in their study estimated that in 1973, 606,827 hearing aids were sold. The Department of Commerce in 1975 put the number sold at 602,187 and in 1972 at 561,191. The difference in these estimates may be explained two ways. One is that the higher figures, in the 600,000 range, represent sales by manufacturers to retail dealers and may include experts. A figure such as 500,000 represents actual purchases of hearing aids by domestic consumers. Certainly one can expect at least some differences between total manufacturers' sales

Table 11

TOTAL SALES OF HEARING AIDS BY DOMESTIC AND MANUFACTURERS TO DEALERS (1970-1975)

Year	Total Sales	Domestic Manufacturers	Imports	Imports as a % of US Sales
1970	464,253	386,116	78,137	17%
1971	529,283	439,217	90,066	17%
1972	561,191	460,598	100,593	18%
1973	582,051	469,458	112,593	19%
1974	585,982	449,935	136,047	23%
1975	602,187	458,204	143,983	24%

Source: Department of Commerce, 1975.

and retail sales to consumers due to inventory stocking. The second explanation is more straightforward: someone's data are simply wrong. The problem with this is that there is no way of knowing which data are correct. Perhaps the best solution is to say that hearing aid sales have been fairly steady over the last several years, hovering between 550,000 and 600,000; and that manufacturers' sales are slightly higher than retail sales.

There are a number of issues involved in the hearing aid industry, centering on how manufacturers and retailers price hearing aids and how they are sold and distributed. These will all be brought together in the next section.

2.2.5 *ISSUES ASSOCIATED WITH HEARING AIDS*

The delivery of hearing care and hearing aids to the American people has come under increasing criticism in the last several years. The Retired Professionals Action Group in its 1973 study, "Paying Through the Ear...", focused the criticism. Both the U.S. Senate and House have held

hearings on the hearing aid industry and its practices. And the HEW Interdepartmental Task Force has prepared a predominantly negative review of the industry. For the purposes of this paper the issues can be categorized as follows: questions about the quality of hearing aids supplied; questions about who should prescribe and supply hearing aids; and questions about how hearing aids are priced. Each of these is highly relevant to Medicaid and its reimbursement policies for hearing aids and is discussed below.

. Quality - In a study done by the New York League of the Hard-of-Hearing, it was found that more than 50% of the hearing aids tested did not meet the claims specified in the manufacturers' advertising. The RPAG report stated that there was "unevenness of product quality..." and that "one aid may differ substantially in performance from (another) aid of the identical model and brand." Finally, the HEW Task Force called for certain minimum standards and suggested areas which should be considered. With the exception of the Veterans Administration and the Department of Defense (which relies on the VA program), virtually no health programs deal with the question of minimum standards for hearing aids. The American National Standards Institute (ANSI) has developed guidelines for evaluation called "Methods for Measurement of Electro-Acoustical Characteristcs of Hearing Aids." It should be stated that these are guides and not used in any hearing aid benefit program. There are also minimum performance specifications developed by the Canadian Government Specifications Board for Hearing Aid Standards. No American program uses these guidelines.

The FDA, in its rules of February 15, 1977, regulates the professional and patient labeling for hearing aids and the conditions of sale of aids. The new labeling regulations require a "User Instructional Brochure" with each hearing aid. This contains specific instructions on such things as use of the aid, maintenance and care, and how to replace the batteries. In addition the brochure also contains technical information in accordance with the test procedures of the Acoustical Society of America Standard for Specification of Hearing Aid Characteristics, ASA STD 7 - 1976. These regulations do not, however, set minimum standards of performance for aids themselves. Questions about device quality therefore remain unresolved and inferior aids continue to be sold. (The regulations may be found in the Appendices.)

Supplying Hearing Aids - Earlier in this paper it was pointed out that over 70% of all hearing aids are purchased directly from hearing aid dealers without examinations by otologists or audiologists. With this fact in mind, a primary issue is whether hearing aid dealers are competent and objective suppliers of hearing aids. First is the question of competence. The training that hearing aid dealers receive is a 20-hour home study course. This training has been criticized by several professional groups and called by the Veterans Administration "inadequate and potentially dangerous." In addition it should be noted that only 15% of hearing aid dealers have this level of training, although many have valuable practical experience.

The issue of competence is somewhat clouded by the conflicting interests of otologists, audiologists, and dealers. The issue of dealer objectivity in selling hearing aids appears more amenable to

analysis. With dealers, there is a built-in conflict of interest because their business is selling hearing aids. Several studies indicate the effects of this conflict. As reported by the HEW Task Force, 85% of those who went directly to dealers were determined to be "capable of being helped" by a hearing aid. However, several studies suggest much lower percentages. A government study in Saskatchewan, Canada, indicated that only 45% of those who contacted audiologists were diagnosed as needing a hearing aid. Studies in Baltimore and New York had much the same sort of results. Both studies found that in a group which had been determined by hearing professionals not to need a hearing aid, hearing aid dealers recommended a hearing aid over 40% of the time.

The reasons behind this situation are clear. The manufacture and sale of hearing aids, unlike other medical devices and pharmaceuticals, are not controlled by a professional writing a prescription or monitored by governmental bodies. The consumer is generally unprotected. Change, nevertheless, is occurring. The FDA, in its February 15, 1977, regulations, has instituted much stricter controls on the sale of hearing aids. These become effective August 15, 1977. As conditions of sale, according to the regulations, the purchaser must have had a medical evaluation of hearing within six months and must have a signed statement from a licensed physician indicating that he or she may be considered a candidate for a hearing aid. Anyone 18 or over may waive this requirement. However, the hearing aid dealer is obligated under the regulation to advise the purchaser that to exercise the waiver provision is not in the individual's best

interest. In addition, the User Instructional Brochure, which must accompany every new hearing aid, must contain a warning statement that a hearing aid dispenser should advise a prospective user to consult a physician (preferably an ear specialist) if the user has any of the following "red flag" conditions: pain or discomfort in the ear; visible ear deformity; a history of drainage; sudden or rapid hearing loss; acute or chronic dizziness; unilateral hearing loss within the previous 90 days; significant cerumen (wax) accumulation or foreign body in the ear canal; and an audiometric air-bone gap equal to or greater than 15 dB at tones of 500, 1,000 and 2,000 hertz. For those under 18 this medical exam prior to purchase cannot be waived. (The regulations are available in the Appendices).

This approach unfortunately has its limits. It does not really address those hearing problems that do not have a specific medical etiology. There is still a vast population of the sensorineural hearing impaired who may or may not need a hearing aid. To help assure that this population receives proper care, one approach is to license hearing aid dealers.

This effort has met with limited success because 40 states have rather loose licensing laws and 10 states have no licensing laws. Among the states that do have licensing laws: only four require a professional examination before an aid can be purchased and the requirement can be waived for those over 17; one requires training at the college level; and only 7 states require training beyond an apprenticeship. Thirty-three states protect the dealer through "grandfather clauses", which permit licensing, in some cases, if the dealer

has been in business for as little as six months. Moreover, licensing requirements vary in degree - for instance, some states require that only the dealer and his store be licensed, but not his salesmen.

The other approach to assure that hearing aids are used appropriately, is to require a prescription from a hearing professional. This is, in fact, what Medicaid does require.

Why then this extensive discussion on dealers? There are several reasons. The first is to point out that Medicaid policy is valid with respect to the requirement about hearing tests prior to the purchase of a hearing aid. The second reason is to describe as fully as possible the relationship and problems that exist in the delivery of hearing care. Also, only by understanding the roles and functions of the hearing aid dealer in supply hearing aids can Medicaid reimbursement for their services be properly analyzed. This subject will be further developed in Section 4, when recommendations are presented.

Pricing - As the Consumers Report article on hearing aids pointed out, the "technical complexity (of) a hearing aid isn't much different from the audio-amplifier section of an ordinary transistor radio with a microphone added." The costs of producing a typical hearing aid were determined by the HEW Task Force. The costs included:

- Parts	$30
- Labor, Advertising, Promotion	45
Total Manufacturer's Cost	$75

The manufacturer sells the hearing aid to a dealer for between $80 and $140. The dealer in turn marks-up the price 200 to 300%.

Table 12

RANGE OF PRICES FOR BEHIND-THE-EAR HEARING AIDS (1972)*

	LOWEST PRICED MODELS		HIGHEST PRICED MODELS	
	Manufacturers Suggested Retail Price	Manufacturers Wholesale Price To Dealers	Manufacturers Suggested Retail Price	Manufacturers Wholesale Price To Dealers
Beltone**	379.00	115.50	449.00	155.00
Danavox	239.00	69.00	399.50	124.50
Fidelity	229.00	99.00	399.50	189.50
Maico	249.50	79.95	379.50	120.95
Norelco	309.00	105.00	370.00	127.00
Oricon	239.50	79.00	397.00	119.00
Qualitone	219.50	57.50	379.50	119.50
Sonotone	350.00	124.00	389.00	149.00
Vicon	249.00	90.00	399.00	110.00
Zenith	195.00	79.00	365.00	125.00

* Prices do not include Cros or Bi-Cros model aids.

**Beltone does not suggest prices. It is well known among dealers that retail price is calculated on a multiple in excess of 3 times the dealer's price.

Source: RPAG, "Paying Through the Ear...", Chapter V, p. 4.

Table 12 provides a graphic description of wholesale and retail prices of hearing aids. Why then these high prices? First a few points on the manufacturer, the retail dealer, and their relationships. As suggested above, the hearing aid industry has a small group of manufacturers which control the market. Whether this is a shared monopoly or oligopoly as the FTC and others maintain, the pricing structure of the industry is remarkably uniform, suggesting virtually no price competition and excessive promotional competition. Beyond the oligopoly rationale for lack of price competition, it has also been pointed out that hearing aid manufacturers perceive the market demand as price inelastic. Simply put, this means that

market demand will not change if prices are raised or lowered. Thus to increase prices is the only way to achieve desired gross revenues and profits. Industry critics have rebutted this argument based primarily on economic analyses. A more trenchant rebuttal, however may be the millions of people who need hearing aids but don't have them because their cost is too great.

Maintaining high prices forms the connection between manufacturers and retailers. Manufacturers wish to keep retail prices high so that they can maintain wholesale price levels. For example, by restricting entry into retail hearing aid sales through exclusive franchises for an area, the manufacturer makes the dealer dependent on one source for his supply. If the dealer tries to cut prices or expand his product line to other brands, the manufacturer will stop the supply altogether. Such activities have been investigated by the FTC, and consent orders to stop these practices have been agreed to by the manufacturers.

The question remains how do retailers rationalize the 200% to 300% markup they take. Both retailers and manufacturers (again interested in maintaining high prices) suggest that the high prices are due to a variety of costs the retailer must sustain. These include everything from time spent in counseling patients and fitting aids to telephone and car expenses. In the retailers' favor it must be said that the very low sales volume makes his operating costs per device quite high. Nonetheless it should be kept in mind that the high prices demanded by manufacturers probably contribute to low volumes. Both the dealer and the consumer are caught in the same situation.

The responses of the HEW Task Force to this situation were to recommend that prices for hearing aids be "unbundled"; that is, the prices of the device should be separated from the costs associated with all the services the dealer performs. This would allow the consumer to choose what costs he or she wishes to incur. This paper will return to this subject and how it relates to Medicaid reimbursement for hearing aids in Section 4, Recommendations.

2.2.6 *SUMMARY*

This paper has examined thus far who provides hearing care, how hearing aids are obtained, and how they are manufacturered and distributed. It has also examined some very timely issues and questions concerning the hearing aid industry as it is currently constituted. In the next section, the methods used by various third party payers to reimburse for hearing aids will be presented as well as how these methods relate to the hearing aid industry.

3. *ALTERNATIVE METHODS OF REIMBURSEMENT FOR HEARING AIDS AND RELATED SERVICES*

In the previous section, hearing aid consumers and the service structure which supplies those consumers' needs were discussed. In this section, the focus will be on various methods of reimbursement for hearing aids used by several public and private health care programs. First, there will be an extensive and specific discussion of how five state Medicaid programs carry out reimbursement for hearing aids. Following that will be brief descriptions of a variety of public and private programs now reimbursing for hearing aids.

These reimbursement methods will be examined in terms of the following:

- Service Fees - This includes consideration of the kinds of fee structure used for diagnostic medical and hearing examinations;
- Product Costs - This includes consideration of the rates and methods used to pay for hearing aids, additional equipment and repairs;
- Quality Control - This includes the steps taken to assure the quality of hearing care and equipment;
- Administration - This includes the methods used to manage a hearing care benefit program.

The purpose of this section is to examine operational methods of reimbursement which could be used in the development of policy for Medicaid programs. Thus, following the presentation of information on reimbursement methods, there will be a summary of the various approaches. Section 4 contains recommendations about the relationships of these approaches to Medicaid policy in terms of compliance with federal statutes, costs, quality, and administration.

3.1 *STATE MEDICAID REIMBURSEMENT POLICIES*

Discussed here are the coverage and reimbursement policies for hearing aids and related services of five state Medicaid programs. The five were suggested by the Medical Services Administration's Division of Policy and Standards and provide a broad range of possible reimbursement configurations.

Prior to specific discussion of the state programs, it is first useful to present some general information on Medicaid and hearing aids. The provision of hearing aids under Title XIX is an optional service. It is a required service, however, for individuals under 21 years of age as part of the Early and Periodic Screening, Diagnosis and Treatment (EPSDT) program (45 CFR 249.10 (A)(3)(iv)).

Of special importance is that Medicaid regulations state that any prosthetic device which a state provides under Medicaid, including hearing aids, must be ordered by a physician or "other licensed practitioner of the healing arts within the scope of his practice as defined by state law."

There is no specific legislative authority to establish reimbursement rates for hearing aids. The pertinent provision in the Act is section 1902(a)(30), which requires only that a state plan must provide that payment for services are not in excess of reasonable charges consistent with economy and efficiency, and quality of care. Accordingly, Departmental Title XIX regulations establish ceilings for reimbursement of services. In the case of hearing aids, the ceiling is specified in 45 CFR 250.30(3)(i)(B),

> "Other noninstitutional services. The upper limits for payment shall be customary charges which are reasonable. The prevailing charges in the locality for comparable services under comparable circumstances shall set the upper limits for payments. In reviewing prevailing

> charges for reasonableness, the State agency should consider the combined payments received by providers (for furnishing comparable circumstances) from the carriers under part B, title XVIII of the Act and beneficiaries under such title, and the combined payments received from other third-party insuring organizations and their regular policy holders and subscribers using whichever of these criteria or other criteria are appropriate to the specific provider service."

According to a survey by ASHA in May, 1976, 17 states provide no speech or hearing services for adults; 33 states provide some of these services; and 25 states provide hearing aids to adults. As mentioned previously, all states must provide hearing aids to persons under the age of 21 through the EPSDT program. Table 13 provides a complete review of hearing benefits available in state Medicaid programs.

With these basic facts in mind, hearing aids and related service coverages and reimbursements in five states, California, Connecticut, Michigan, New Jersey and Washington are reviewed next.

Table 13

MEDICAID COVERAGE FOR SPEECH AND HEARING SERVICES BY STATE - MAY, 1976

	No Speech and Hearing Services Provided	Speech and Hearing Services Provided in Some Form	Hearing Aids Provided to Adults
Alabama	X		
Alaska	X		
Arizona		X[1]	
Arkansas		CN/MN	
California		CN/MN	CN/MN
Colorado		CN	
Connecticut		CN/MN	CN/MN
Delaware		CN	
D.C.	X		
Florida	X		
Georgia	X		
Hawaii		CN/MN	CN/MN
Idaho			
Illinois		CN/MN	CN/MN
Indiana		CN	CN
Iowa		CN	CN
Kansas		CN/MN	CN/MN
Kentucky		CN/MN	
Louisiana		CN	CN
Maine		CN/MN	
Maryland	X		
Massachusetts		CN/MN	CN/MN
Michigan	X		
Minnesota		CN/MN	
Mississippi	X		
Missouri	X		
Montana		CN/MN	CN/MN
Nebraska		CN	CN
Nevada		CN	CN
New Hampshire		CN/MN	CN/MN
New Jersey		CN	
New Mexico		CN	CN
New York		CN/MN	CN/MN
North Carolina	X		
North Dakota		CN/MN	CN/MN
Ohio		X[2]	X
Oklahoma	X		
Oregon	X		CN
Pennsylvania	X		
Rhode Island	X		
South Carolina		CN	
South Dakota		CN	
Tennessee	X		
Texas	X		
Utah		CN/MN	CN/MN
Vermont		CN/MN	CN/MN
Virginia		CN/MN	
Washington		CN/MN	CN/MN
West Virginia		CN/MN	CN/MN
Wisconsin		CN	CN
Wyoming	X		
TOTALS	18	33	25

CN - Categorically needy only
MN - Medically needy only
CN/MN - Categorically and medically needy
1 - Medicaid program proposed to begin July 1, 1976
2 - All speech and hearing services discontinued as of May 1, 1976

Source: American Speech and Hearing Association, May 1976

3.1.1 *CALIFORNIA*

Limits on hearing services are both comprehensive and detailed under Medi-Cal. A hearing aid is covered: "only when supplied by a hearing aid dispenser on prescription of an otolaryngologist, or the attending physician when there is no otolaryngologist available in the community, plus an audiological evaluation which must be performed by or under the supervision of the above physicians or by a certified audiologist."

Within this general framework limits on hearing care services and equipment are as follows:

- Examinations - Under general Medi-Cal provisions, both physicians and audiologists are limited to supplying a maximum of two services in any one month to a recipient; and no more than 24 services in 12 months. EPSDT patients are exempt from this limitation.
- Equipment - As stated earlier, a patient must be examined by an otologist or other competent physician and an audiologist before Medi-Cal will reimburse for a hearing aid. Prior authorization is required for the purchase or trial period rental of hearing aids and for repairs that exceed $10.00 per service. However, batteries, cords, receivers, ear molds, and hearing garments are covered without prior authorization.

When requesting authorization for a hearing aid, the results of the following tests must be included: A pure tone air conduction threshold test of each ear at 500, 1,000, 2,000, and 4,000 Hertz; speech tests including Speech Reception Threshold (SRT), Speech Discrimination Score (SDS), and Sound Field Aided and Unaided.

Based on these tests, a hearing aid may be authorized if the results indicate the following: if after any medical treatment, hearing loss in the better ear is 35 dB or greater from 500, 1,000, and 2,000 Hertz; or when the difference between the level of 1,000 and 2,000 Hertz is 20 dB, or more, the average air conduction threshold at 500 and 1,000 Hertz need only be 30 dB to qualify.

A hearing aid may not be replaced more often than once every three years except when the recipient certifies that he or she has lost the aid or when the hearing impairment requires greater amplification.

Binaural hearing aids may also be authorized when the hearing loss is associated with blindness, when the hearing loss is 30 dB in both ears for those under 18, and when the hearing loss in both ears is 35 dB for those 18 years old and above.

Allowable fees and charges for the services and equipment discussed above are as follows:

. Otologists - Otolaryngologists, Otologists, and other qualified physicians are reimbursed for hearing services based on the 1969

California Relative Value Scale (RVS) or usual and customary charges, whichever is lower. In the case of the examining physician, there are two sets of charges he or she may make. First is the complete ear, nose, and throat check-up and second is audiometric testing. Selected charges for such procedures are presented in Table 14. To arrive at a fee, the RVS unit value is multiplied by the conversion factor.

Table 14

SELECTED OTOLOGISTS SERVICES WITH RVS UNIT VALUES
CONVERSION FACTORS AND RESULTING FEES AS OF OCTOBER 1, 1976

Services	RVS Unit Values	Conversion Factor	Fee
Initial limited history and physical exam.	30.0	.69	$20.70
Initial intermediate history and physical exam.	50.0	.69	$34.50
Initial comprehensive history and physical exam.	70.0	.69	$48.30
Audiometric hearing test, plus tone (air only) screening	10.0	.69	$ 6.90
complete, air, audiogram	15.0	.69	$10.35
air and bone, with or without masking	20.00	.60	$13.80

. Audiologists - Reimbursements for audiologist are made based on a schedule of maximum allowances or usual charges made to the public, whichever is lower. Examples of maximum allowable fees for audiologists may be found in Table 15.

Table 15

MAXIMUM REIMBURSEMENT ALLOWANCE FOR
SELECTED AUDIOLOGICAL SERVICES DECEMBER, 1976

Services	Maximum Allowances
Diagnostic audiological evaluation, including pure tone audiometry, speech reception threshold and discrimination	$29.70
Hearing aid evaluation only (following above procedure)	$17.90

. Equipment - Medi-Cal reimbursements to dealers for hearing aids, accessories, and services are based on a schedule of maximum allowances not to exceed usual and customary charges to the general public. In all cases, the maximum allowance for a monaural hearing aid is $281.88 and for a binaural instrument the price of two monaural instruments less $82.00, or a total of $512.50, whichever is less. Table 16 presents maximum allowance for specific kinds of hearing aids.

In addition, all instruments must be guaranteed at least one year and repaired instruments for at least six months. Batteries, cords, and other authorized accessories are reimbursed at the lower of retail prices or dealer cost plus 50%. Charges for repairs after the guarantee period may use customary markup procedures but may not exceed the invoice cost to the dealer plus 100% to a maximum mark up of $25.62, or the factory retail price for the repair service, whichever is lower.

Table 16

MEDI-CAL MAXIMUM ALLOWANCES
FOR SELECTED HEARING AIDS

Manufacturer/Model	Description	Maximum Allowance
Beltone Vocale	Eyeglasses	$256.36
Beltone Prelude	Behind-the-Ear	252.07
Beltone Largo	Body	248.80
Dahlberg DM-1219	Eyeglasses	237.89
	(binaural)	378.00
Dahlberg CJ-1248	Behind-the-Ear	244.30
Dahlberg EH-1234	Body	254.78
Maico BF	Eyeglasses	259.68
Maico BI&BJ	Behind-the-Ear	253.15
Maico CB&CC	Body	260.38
Sonotone 35	Eyeglasses	265.43
Sonotone 76	Behind-the-Ear	265.43
Sonotone 600 C	Body	273.03

If the recipient does not have a custom ear mold and the mold is not included in the instrument price, the following maximum allowances apply:

Standard custom ear mold	$ 8.20
Silhouette or rising ear mold	12.30

The cost to the Medi-Cal program for supplying an average hearing aid may be summarized as follows:

. Initial intermediate exam by an otologist	$ 34.50
. Audiometric hearing test, complete	10.35
. Behind-the-Ear Aid (average)	250.00
. Custom ear mold	8.20
Total	$303.25

or

. Initial intermediate exam by otologist	$ 34.50
. Hearing aid exam by audiologist	17.90
. Behind-the-Ear aid (average)	250.00
. Custom ear mold	8.20
Total	$310.80

Medi-Cal maximum reimbursement allowances for hearing aids were last published in November, 1972. The 1972 prices were increased by 6% after an extensive study completed in May, 1974. This study, performed by the Rates and Fees Section of the Department of Health, provides an excellent background on the hearing aid industry and includes useful analyses of the results of a survey of hearing aid dealer costs.

The cost survey was sent to 103 California dealers, and 23 replies were received. Although a small sample responded, the study concluded that the results were usable based on comparisons with a Michigan study done in 1971 which indicated very similar findings.

The study, using 1972 figures, found that the monthly average sales of a hearing aid dealer were $4,408.99. Of this amount, $3,339.90 or 76% were for hearing aids. The remaining sales were divided into accessories, 15% of sales, repairs, 7% of sales, and "other", 2.7% of sales. As to the monthly cost of goods, hearing aids represented $1,188.96 or 67% of total costs of goods. Accessories accounted for $402.75 or 22.7% of costs of goods. The remaining 10% was allocated to repairs and "other". Thus, total sales of $4,408.99 less total cost of goods or $1,774.92 gives a gross profit before expenses and income tax of $2,634.07.

The study then defined the average business expenses and net profit. Their findings are reproduced in Table 17.

Using the $1,256.31 in reimbursable expenses, this study then allocated these expenses first to hearing aid sales in total and then to each hearing aid sold. This was done by taking the percentage of total sales represented by hearing aids, 75%, and applying this percentage to total expenses. The result was $951.68. They then divided the number of hearing aids sold per month in 1972, 10.4, into this total and found that the expense per aid was $91.51. Based on this number, they projected the expense per aid in 1974 by multiplying by 1.062 (assuming an inflation rate of 6.2%). The projected business expense per aid came to $103.31.

A similar process was followed to calculate allocations of expenses for accessories and repairs. In the case of accessories, the study found that the proportion of allocable business expenses to invoice cost was 45.9%. With major repairs, the projected business expense per hearing aid repair in 1974 was $14.68.

The California study then calculated net profit per hour based on a monthly net profit of $1,120.98 and 173.33 working hours per month. The hourly net profit came to $6.47. Using this hourly rate the study priced dispenser services on the basis of actual time expended. They believed that this "yields a realistic value for necessary services actually rendered by hearing aid dispensers". Selected values for various services as determined by the study are presented in Table 18.

Table 17

HEARING AID DISPENSER
AVERAGE BUSINESS EXPENSES AND NET PROFIT*
(JANUARY 1, 1972 THROUGH DECEMBER 31, 1972)

Category	Monthly Average			
REIMBURSABLE BUSINESS EXPENSES:				
Salaries and wages	$273.28	(18.1%)		
Employee Benefits	32.51	(2.2%)		
Supplies	83.52	(5.5%)		
Rents and Leases (building and equipment)	214.04	(14.2%)		
Utilities	25.81	(1.7%)		
Communications	82.06	(5.4%)		
Accounting Services	19.80	(1.3%)		
Professional Services	5.71	(0.4%)		
Depreciation (building and equipment)	55.48	(3.7%)		
Business Taxes and License	29.64	(2.0%)		
Insurance	33.81	(2.2%)		
Interest	16.59	(1.1%)		
Travel	118.93	(7.9%)		
Association Dues	17.00	(1.1%)		
Advertising (1/3 allowed)	53.02	(3.5%)		
Other	195.11	(12.9%)		
SUBTOTAL			$1,256.31	(83.0%)
NONREIMBURSABLE BUSINESS EXPENSES:				
Commissions	$118.71	(7.8%)		
Bad Debts	20.53	(1.4%)		
Contributions	2.22	(0.2%)		
Claims and Settlements	1.81	(0.1%)		
Christmas, Promotions, Sales Meetings	7.48	(0.5%)		
Advertising (2/3 disallowed)	106.03	(7.0%)		
SUBTOTAL			$ 256.78	(17.0%)
Total Business Expenses			$1,513.09	(100.0%)
Gross Profit			$2,634.07	
Less Total Business Expenses			-1,513.09	
Net Profit (before income taxes)			$1,120.98	
Net Profit Per Hour (173.33 hours equal one month)			$ 6.47	

*Based on cost reports from 23 licensed hearing aid dispensers

Source: Hearing Aid Study Report, Report No. 35-74-1, Rates and Fees Section, California Department of Health, May, 1974.

Table 18

VALUE OF HEARING AID DISPENSERS SERVICES

Service	Average Time (hours)	Value ($)
Hearing Aid		
Prefitting Visit	1.0	$ 6.47
Fitting	1.75	11.32
Post Fitting Visit (4 at 40 minutes each)	2.67	17.28
Total Hearing Aid Service	5.42	$35.07
Repairs		
Major	0.5	$ 3.24
Minor	0.42	2.72
Accessories	0.2	1.29
Ear Molds	0.75	4.85

Based on these findings, the report recommended numerous revisions to the maximum allowances for hearing aids. These include a 15% increase in the allowance for a monaural hearing aid and a 20% increase for a binaural aid. For major repairs, the study suggested a decrease from $25.62 to $18.00. The study also recommended that a separate reimbursement procedure code be established for minor repairs and that a maximum allowance be set at $5.75 for this service. This would eliminate the ability of a dealer to perform minor repairs and charge the maximum allowance of $25.62.

The fiscal impact of these recommendations was also considered by the report. The current annual cost of hearing aids to the program at the time of the study was $4,960,220. With the changes suggested, the annual program

cost would rise to $5,431,353 or about 10%. As suggested earlier, rather than this recommended change the maximum allowance for hearing aids was adjusted upward 6%.

3.1.2 *CONNECTICUT*

The hearing aid program in the Connecticut Medicaid program is currently in flux. New procedures and reimbursement rates have been prepared but are now being challenged by the hearing aid dealers. The information below therefore covers both current and proposed rules governing hearing services and hearing aids in the Connecticut program.

The Connecticut Medicaid program covers all recipients for hearing care and equipment. In 1975, preliminary data on the program showed that 248 hearing aids and 96 batteries were supplied to AFDC recipients. Total expenditures for hearing aids, again in 1975, was $10,506.63 for the categorically needy and $714.91 for the medically needy, a total of $11,220.54. These data are highly questionable because they suggest only about $50.00 per hearing aid. Nevertheless, they do suggest the very small magnitude of the program.

Limitations on services and equipment available to recipients are as follows:

- Examinations - There are no specified limits on the number of services which may be provided by otologists or audiologists. A hearing aid, however, cannot be authorized for payment without meeting the following requirements:

  "A written report and recommendation of an otologist, otolaryngologist or pediatrician to include the diagnosis and the clinical

pathology, if any. Or, a written report and recommendation of a physician as described above plus the detailed evaluation of an audiologist from a clinic or center with programs qualified and/or registered with the Professional Services Board of American Speech and Hearing Association, when a person is referred to such a center for further testing by the physician."

Under the proposed rules this procedure would remain in effect. There would be the additional requirement that an audiological examination be carried out in all cases either by the physician or the audiologist.

. Equipment - As suggested above, to obtain a hearing aid, the recipient must have a written recommendation from a physician or from a physician and an audiologist. Based on this, the Medicaid program, with the approval of the Medical consultant, will authorize a hearing aid for the recipient. There are no further specified restrictions on limitations as to minimum hearing loss, the number of hearing aids, or how often they may be dispensed. The proposed policy does not change or add to these requirements.

Allowable fees and charges for the services and equipment discussed above are:

. Examinations - Reimbursements for physicians in Connecticut are based on the 1964 California Relative Value Studies. The allowances for otological services are presented in Table 19.

Reimbursement rates for audiologists are based on a fee schedule. Their charge related to hearing aids, a speech and hearing exam, has a maximum fee of $25.00. These fees are not affected by proposed changes in the hearing aid policy.

Table 19

ALLOWABLE FEES FOR OTOLOGICAL SERVICES

Services	Fee
Initial Visit	$15.75
Follow-up Visit	9.00
Audiometric Test (Pure tone only)	5.00
Audiometric Test (Air and bone conduction)	10.00

. Equipment - Currently, the Connecticut Medicaid Program reimburses for hearing aids at the retail price less a minimum of 20%. Hearing aids must have a one year guarantee against defects in materials and workmanship, and must be all transistor and come with battery. The reimbursement for a custom ear mold is $12.00. All repairs to hearing aids will be authorized only on the basis of itemized estimates or cost, submitted by the provider prior to repair. There are also schedules for batteries and cords.

In the proposed policy, all hearing aids must be priced based on the single lot cost to the dealer plus a $125.00 fee not to exceed $250.00. To assure compliance, the Department of Social Services will require from dealers statements of wholesale price lists of aids available. Exceptions to this policy will be considered individually by the program.

Based on the above information, a hearing aid would cost the Connecticut Medicaid program approximately the following:

. Physician examination	$ 15.75
. Audiometric test	5.00
. Ear mold	12.00
. Hearing aid (at an average price of $350, less 20%)	280.00
Total	$312.75

or,

. Physician examination	$ 15.75
. Audiological examination	25.00
. Ear mold	12.00
. Hearing aid (same as above)	280.00
Total	$332.75

Under the new policy the totals in both cases would be reduced at a minimum by $30.00.

The proposed changes in hearing aid reimbursement policy were first set forth in October, 1976, and were based on a review of much the same literature referenced in Section 2 of this report. The analysts in Connecticut found that the wholesale price of hearing aids was relatively low but that a very high markup was added to achieve the retail price. They also found that one supplier was willing to sell hearing aids to the state for between $90 and $150. This supplier however had been denied a license by the state hearing aid dealer board and had been harassed for his practice of underselling hearing aids. This led the analysts to conclude that the price paid for a hearing aid could be reduced, thus the recommendation for a cap of $250.00.

The proposed policy has been issued as draft rules by the Connecticut Department of Social Services. At this writing, the rules are being contested in state hearings by the dealers. The latter maintain that the $250.00 limit is too low especially given the rise in their costs over the last several years.

Several other proposals have also been made as part of an overall reconsideration of hearing aid reimbursement. Among these is a proposal to volume purchase hearing aids. Another is a plan to work with prison industries in developing a hearing aid repair shop and ear mold lab. Perhaps most important, Connecticut is considering requiring hearing aid dealers to disclose operating costs so that future reimbursement schedules may be accurately developed.

3.3.3 *MICHIGAN*

The Michigan Medicaid Program provides hearing care services and equipment to those qualfied for the EPSDT program through Title V, the Crippled Children Program. For those Medicaid recipients over 21, it is still possible to receive a hearing aid if the recipient is in the categorically needy group. The Michigan Medicaid officials estimate that about 1,500 hearing aids are purchased per year at a total cost of around $500,000.

The services and equipment available to Medicaid beneficiaries are subject to the following limitations:

- Examinations - The services of a physician may be used by a recipient with an ear or hearing problem. However, to receive a hearing aid all that is required is an audiological examination by an audiologist. The program requires that any examining audiologist

must be associated with a speech and hearing center and that prior approval must be obtained to carry out diagnostic services related to hearing aids. Prior approval is obtained from the Regional Audiology and Speech Consultant of the Department of Public Health.

. Equipment - All services and equipment provided by a hearing aid dealer must have prior approval. A hearing aid cannot be dispensed without such approval and can only be dispensed when ordered by an accredited audiologist. Furthermore, only one hearing aid can be acquired per year.

The fees and rates for hearing aid services are presented below:

. Examinations - Reimbursements for otologists is paid according to the physicians' fee schedules. Reimbursements are not paid directly to audiologists, but to Speech and Hearing Centers. These Centers' fees must be either usual and customary charges or prevailing, whichever are less. Actual dollar figures for fees and sales vary, however. Table 20 presents estimates of usual fees for hearing related examinations.

Table 20

ESTIMATED FEES FOR SELECTED EXAMINATIONS
RELATED TO HEARING AIDS

Service	Fee
Otologist intermediate exam	$20.00
Physician fees for hearing tests	
Air only	11.00
Air and bone	16.00
Speech and Hearing Center Fees	
Basic hearing evaluation	22.00
Hearing aid evaluation and testing	15.00

. Equipment - The reimbursement rate for a hearing aid in Michigan is the single lot cost of the aid to the dealer plus $180.00 in dealer's fees. According to Michigan officials, the average total cost is about $325.00. This reimbursement covers: the specified hearing aid; all necessary cords, tubing, and connections; one-year guarantee against defective parts and assembly; one ear mold per hearing aid guaranteed for 90 days or two ear molds for a bilateral hearing aid; one receiver or oscillator per aid, or two for bilateral aid; six batteries per aid; and one carrier garment per aid, if required.

Reimbursements for repairs to hearing aids not under warranty is cost plus 100% or cost plus $30.00, whichever is less. The provider's reports and invoices must be available for review. Where a hearing aid is loaned to a recipient while repairs are being made or when delivery of a new aid is delayed, the provider may charge an additional amount not to exceed $10.00.

The total cost of a hearing aid to the Michigan Medicaid program is, on average, the following:

Audiological hearing aid exam	$ 15.00
Average cost of hearing aid	325.00
Total	$340.00

With the services of a physician it could be as follows:

Medical exam	$ 20.00
Audiological exam (by physician)	11.00
Hearing aid	325.00
Total	$356.00

The hearing aid reimbursement rates were developed through discussions with hearing aid dealers and a study performed in Michigan in 1971. The cost audit was done by the Auditor General's office and included review of 25 dealers or 17% of all dealers in the state. Sales, cost of sales, and various expenses were obtained from the dealers' financial records. Expenses applicable to hearing aids were determined by allocating total business, selling, and administration costs on the proportion of hearing aid sales to total sales. The number of hearing aids sold was determined by review of invoices, manufacturers' reports, and commission sales report records. The results of this survey may be found in Table 21. The average sales price was found to be $329.63 and the net income per hearing aid, excluding commission and donations was found to be $104.93. With this study and negotiations with the dealers, the reimbursment rate was increased to bring Medicaid reimbursements in line with the charges made to the general public.

3.1.4 *NEW JERSEY*

The New Jersey Medicaid Program covers hearing services and hearing aids for all those eligible for the program. The following limitations on services and equipment are applied in New Jersey:

- Examinations - There are no specified limits on the number of visits to otologists or audiologists. To obtain a hearing aid however, the recipient must have both a medical and an audiological examination. An otologist or otolaryngologist must perform the medical examination and document the need for a hearing aid. Either the physician or an audiologist must do a complete audiological

TABLE 21

Hearing Aid Dealer

Average Sales and Expenses for the 1971 Tax Year

(Michigan State Department of Public Health)

Average Hearing Aid Sales Price		$329.63
Less Average Wholesale Cost 1/		-127.29
Average Gross Profit per Hearing Aid		$202.34
Average Hearing Aid Selling and Administrative Expense 2/	$135.33	
Less Average Commission and Donations Expense	-37.92	
Average Selling and Administrative Expense; Excluding Commissions and Donations		97.41
Average Net Income per Hearing Aid; Excluding Commissions and Donations		$104.93
Number of Dealer Businesses Included		25

1/ Includes invoice cost of hearing aids, batteries, ear mold, and other components normally supplied during the initial sale.

2/ Includes accounting, advertising, automobile, building, equipment rental and depreciation, salaries, office expenses, commissions, taxes and licenses, interest, and other business expenses deductible for proprietorship federal income tax reporting purposes.

Source: Report #35-74-1, Rates and Fees Section, California Department of Health, May, 1974, p. 12.

examination. This includes: pure tone air-bone conduction; masking audiometry, when indicated; speech reception threshold; speech discrimination; and tolerance level for speech and threshold discomfort. It should be noted that audiologists are not considered providers in the New Jersey program. Their services must be billed either through the physician or through a speech and hearing clinic.

. Equipment - All hearing aids must be prior authorized. To get such approval, the hearing aid provider must present the otolaryngological examination, the audiologic evaluation, and the audiogram to the Local Medical Assistance Unit. The provider must also submit the following data: the manufacturer and model of the aid; the number of batteries and type; the type of custom ear mold; if indicated by the model, two cords, receiver model and hearing aid garment, and the unit price. In addition, all repairs to hearing aids must have prior approval.

Binaural hearing aids are allowed only for children, for adults attending school, or for an eligible adult recipient who is gainfully employed or who is likely to be employed if a binaural hearing aid is provided. In general, a person 18 or over can receive a new hearing aid only every two years and every one year if under 18. A medical examination is not necessary to obtain a new aid under these circumstances, but an audiological test is required.

Allowable charges for hearing examinations and hearing aids are as follows:

. Examinations - Physician services are billed according to the customary charge prevailing in the community not to exceed an allowance determined reasonable by the Medicaid program.

. Equipment - Reimbursements for hearing aids are limited to the manufacturer's listed retail price of the aid less 20%. In those cases where a suggested listed price is not available, the limit may not exceed twice the dealer's cost less 20%. In reimbursing for an aid, the provider is required to supply to the recipient: a new instrument, a custom ear mold, one month's supply of batteries; all necessary cords; a garment bag or other standard accessories; and a one year guarantee against defects in materials and workmanship. Furthermore, the provider must guarantee the fit of the instrument and must supply the aid within 21 days. The provider also agrees to accept the return of an aid within 21 days if the prescribing otologist or audiologist determines that the aid does not conform to specifications.

Reimbursement for repairs and batteries are based on customary charges not to exceed an allowance established by the program. Batteries may be obtained without prior approval and billed directly to the Medicaid program.

3.1.5 *WASHINGTON*

The Washington Medicaid Program as will be seen below has different practices for the examination portion of acquiring a hearing aid. Otherwise the reimbursement is similar to the other states previously discussed. The Medicaid Program in Washington will supply a hearing aid to both EPSDT children and to those eligible over age 18. According to state officials, approximately 800 hearing aids are reimbursed for annually at a total cost

of $250,000. This means that the average hearing aid in Washington costs $312.00

The following limits on hearing services and equipment apply in Washington:

- Examinations - The Medicaid program does not reimburse for otologists or audiologist relative to determinations of need for a hearing aid. Instead the hearing aid dealer carries out the examination. The program does pay for physicians' services related to medical problems of the ear. This situation does not apply to EPSDT patients whose examinations are covered by the Crippled Children Program.
- Equipment - To obtain a hearing aid, the patient must have a hearing loss of 50 dB as determined by the hearing aid dealer. The results of the test must be submitted to the state, which then authorizes purchase of the hearing aid.

Rates and fees for hearing services and equipment are as follows:

- Examinations - Because audiologists and otologists are not reimbursed for hearing aid examinations, there are no fees associated with examinations.
- Equipment - The state pays the retail price of the hearing aid less 20% up to a maximum allowance of $325.00. The state does not reimburse for binaural or other more expensive models without special consideration. The program requires that the hearing aid have a trial period of 30 days and that it be guaranteed for one year. The state does not pay for repairs or batteries but will pay a one-time repair bill for a privately acquired hearing aid.

The state Medicaid program is now reevaluating the whole hearing aid program. This includes:

- Review of testing provided by the hearing aid dealers;
- Consideration of how to conform with recent FDA regulations regarding hearing aids;
- The possibility of implementing a purchase program patterned after the VA; and
- Review of actual costs of hearing aid dealers.

3.2 *PROGRAM REIMBURSEMENT POLICIES FOR HEARING AIDS (other than Medicaid)*

The following additional programs were examined for their reimbursement methods:

3.2.1 *VETERANS ADMINSTRATION*

The Veterans Administration's approach to supplying hearing aids to former members of the Armed Forces is unique among public and private health programs. Not only does the VA purchase hearing aids in volume on a bid and contract basis; it also conducts annual tests on about 100 different types of aids to determine the quality of their performance.

According to testimony delivered before a Senate panel investigating hearing aids, by Dr. Lyndon E. Lee, Jr., Assistant Chief Medical Director for Professional Services, the VA issued some 14,000 hearing aids in Fiscal Year 1974. Nearly 11,100 of these aids were issued to VA beneficiaries, costing $1,135,188. The remaining 3,300 aids were issued to persons employed in the military services and other governmental agencies.

According to further statistics provided by the VA's Dr. Lee, the per capita cost to issue a hearing aid amounts to $205.00 -- the lowest such

cost for any health program. An itemization of this unit cost per hearing aid is as follows:

Item	Cost
. Hearing Aid	$108.00
. Aural Rehabilitation	7.00
. Salaries (related to audiological exam and hearing aid evaluation)	40.00
. Hospital cost per visit	30.00
. Travel cost per visit	8.00
. Ear Mold (impression, packaging, handling)	12.00
Total	$205.00

Veterans are issued hearing aids at one of 45 VA Audiology and Speech Pathology Clinics. These clinics are staffed by 332 university trained speech and hearing specialists, plus another 38 trainees. About 100 regular staff and 65 trainees are involved in the hearing aid portion of the communicative disorders program. Further, about 25 percent of the overall audiology time and workload is assigned to hearing aid related duties.

As explained by the VA Medical Chief:

> "The procedure for obtaining a hearing aid from the VA is simple. The veteran who is eligible for treatment of hearing disability applies for a hearing aid to the nearest VA facility. He is given an appointment for an otological examination followed by an audiological examination. Upon determining need for a hearing aid, a hearing aid evaluation is conducted. When the veteran has been issued a particular hearing aid, the Hines Supply Depot is notified, and a replacement aid is sent immediately to the clinic. In addition, the Prosthetic Distribution Center in Denver is notified regarding the hearing aid issued. The veteran is given a two-week supply of batteries when he receives his hearing aid from the clinic, and the Denver

Prosthetic Distribution Center sends him a 90-day supply of batteries for that instrument and an order form. Later when the veteran has only a two-week supply left, he notifies the Prosthetic Distribution Center by the postcard order form, and another 90-day supply is provided him. In addition, he also receives from the Prosthetic Distribution Center a pre-addressed mailing carton with instructions relating to packaging of the hearing aid and sending it to the Center any time it requires repair services. Minor repairs and maintenance services are completed at the Center. The instrument needing factory repairs is sent to the manufacturer or other commercial repair facility. The repaired hearing aid is returned to the Center to determine if it has been satisfactorily repaired before being sent to the veteran. For the hearing aids currently issued, manufacturers have provided VA with a two-year warranty."

Hearing aids procured by the VA are obtained from manufacturers on a bid and contract basis. In Fiscal Year 1975 there were 33 hearing aid models on contract (out of a possible 500). The VA is able to limit the number of models and related inventory because since 1955 it has tested the quality of hearing aids before it agrees to purchase them in volume.

This testing is conducted by the National Bureau of Standards and the University of Maryland's Biocommunication Laboratory, whose results are analyzed by the VA's Auditory Research Laboratory in Washington, D.C. Testing and analysis are performed in part under guidelines established by the VA's Panel on Hearing Aid Performance. The results of these evaluations are sent to the manufacturers who submitted aids for review; and, an annual report of these activities is published as "Hearing Aid Performance Measurement Data and Hearing Aid Selection Procedures."

As to the actual testing procedures, a manufacturer is limited to submission of seven different models. These models are as follows.

- hearing aids adjusted to yield a 6 dB per octave rise;
- hearing aids adjusted to yield minimum amplification below 1000 Hertz and maximum amplification above 1000 Hertz;

- compression hearing aids;
- bone conduction eyeglass hearing aids;
- directional hearing aids;
- BICROS hearing aids; and
- in-the-ear hearing aids.

Choosing the hearing aids for contract is based on the following items:

- those that have the lowest cost per point of quality as obtained by dividing the determined cost to the VA by the Index of Characteristics score obtained as a result of the measurements; or
- those that may be deemed medically necessary to provide adequate hearing rehabilitation for deafened veterans without reference to their measurement results or cost per quality point; or
- those that have Index of Characteristics scores which are significantly better than the other hearing aids in their category; or
- those that may be deemed necessary for research purposes.

The Index of Characteristics may be defined as performance scores derived by applying weighting factors (which have been reviewed and approved by the VA advisory group) to the test results.

3.2.2 *PRIVATE PLANS*

Of the private plans reviewed, Blue Cross/Blue Shield, United Mine Workers of America, and United Auto Workers, only the last organization had a definitive arrangement for providing hearing aids. This benefit is shown in Exhibit 2 on the following page. No cost data are available for this program.

Exhibit 2: Hearing Aid Expense Benefits Provided in UAW-Chrysler Benefit Plan*

An important new benefit will provide coverage for hearing aids and related services. These new benefits will be made available to persons covered under the health care benefits program. The program will include retirees and surviving spouses, and their dependents, as well as active employes with one or more years of seniority and their dependents. All other health care (other than dental) eligibility rules are applicable.

The benefit works as follows:

1. A member must first have a prescription recommending a hearing evaluation from a doctor specializing in hearing problems. This visit is not paid for by the program.
2. The member than obtains an audiometric (hearing evaluation) examination. This may be performed by a doctor or a qualified audiologist, who prescribes a specific type or brand of hearing aid. The plan pays for these services.
3. The hearing aid dealer fills the prescription and fits the hearing aid. The plan pays for the service and the instrument.
4. A follow-up visit to the doctor or audiologist to determine the effectiveness of the hearing aid will also be paid for.

Members will not have to pay anything out-of-pocket when services and hearing aids are obtained from participating audiologists and dealers. But no payments will be made to non-participating providers.

Benefits are available once every three years.

Measures will be designed to assure the quality of hearing aids and professional services.

*This plan is virtually identical to those UAW negotiated with Ford and General Motors.

Blue Cross/Blue Shield do not normally cover hearing aids, but will pay for hearing examinations.

The United Mine Workers of America pay for hearing aids on an "as billed" basis after certification of need by an otologist. Invoices are screened for reasonableness at one of seven district offices around the country.

3.3 *SUMMARY*

The various approaches to reimbursement for hearing aids in five Medicaid programs have been outlined above. The various fees and allowances for both examinations and equipment are summarized in Table 22. It should be noted that this table presents average costs for hearing aids and, generally, maximum allowances where applicable for examinations. The figures in the Table should be considered only as approximations; no state except Washington could confirm a true average cost. Nonetheless, it is felt that the figures given represent a valid range of hearing examination and equipment costs.

As can be seen in Table 22, the costs of hearing aids among the states do not vary a great deal. In all cases, the average total reimbursement is between $300.00 and $350.00. Although figures on New Jersey examination reimbursement rates were not available, it is very unlikely that they would fall outside this range. The equipment reimbursement rates alone fall between $258.00 and $325.00. This range results from the fairly tight allowances in California as opposed to the less stringent controls in Michigan.

Table 22

AVERAGE COSTS ASSOCIATED WITH HEARING AIDS IN FIVE MEDICAID STATES

	CALIFORNIA		CONNECTICUT		MICHIGAN		NEW JERSEY		WASHINGTON	
	Otologist Only	Otologist/ Audiologist	Otologist Only	Otologist/ Audiologist	Otologist Only	Otologist/ Audiologist	Otologist Only	Otologist/ Audiologist	Otologist Only	Otologist Audiologist
A. Examinations										
. Medical	$ 34.70	$ 34.70	$ 15.75	$ 15.75	$ 20.00	(A)	N/A	N/A	(B)	(B)
. Audiological	10.35	17.90	5.00	25.00	11.00	$ 15.00	N/A	N/A	(B)	(B)
TOTAL	$ 45.05	$ 52.60	$ 20.75	$ 40.75	$ 31.00	$ 15.00	N/A	N/A	0	0
B. Equipment									Limit is $325.00	Limit is $325.00
. Ear mold	$ 8.20	$ 8.20	$ 12.00	$ 12.00			$280.00	$280.00		
. Hearing aid	250.00	250.00	280.00(d)	280.00(d)	(E)	(E)	(d)	(d)		
. Dealer fee	(C)	(C)								
TOTAL	$258.20 (f)		$292.00	$292.00	$325.00(g)	$325.00(g)	$280.00	$280.00	$312.00(h)	$312.00(h)
C. TOTAL (A+B)	$303.25	$310.80	$312.75	$332.75			N/A	N/A	$312.00	$312.00

(A) Medical exam not required in Michigan
(B) Medical or audiological exam not required; testing done by dealer
(C) Average maximum of a monaural behind-the-ear aid
(d) Reimbursement is retail cost less 20%, thus using average cost of $350.00 less 20%
(e) No limit on cost of hearing aid, but must be single lot wholesale cost
(f) Limit is $281.88 for monaural and $512.50 for binaural
(g) Estimated average by Michigan officials
(h) Actual average cost of hearing aid in Washington

Overall the Medicaid programs' patterns of reimbursement may be summarized as follows:

- All programs require prior approvals before a hearing aid can be obtained.
- California, Connecticut, and New Jersey all require both a medical examination and an audiological examination; however, Michigan requires only an audiological exam, and Washington depends solely on hearing aid dealers to carry out testing.
- Connecticut, New Jersey, and Washington reimburse on retail prices less 20%; California has specific maximum allowances, and Michigan has only a maximum allowance on the dealer fee.
- Only one program, Michigan, differentiates the prices of the hearing aid from the dealers' fees.
- No program has specific quality control guidelines for hearing aids, except a requirement that the aids be guaranteed for a year.
- In most cases, follow-up of the patient once the hearing aid is dispensed is not an integral part of the program.
- The costs associated with audiological testing appear to be lower when carried out under the auspices of the physician.
- State Medicaid hearing aid programs are fairly small and are basically controlled by the medical consultant and appropriate field representatives.
- Only California and Washington set specific criteria (levels of hearing loss in decibels) for obtaining a hearing aid.

. All states either explicitly or implicitly control how often a hearing aid may be replaced. California sets time limits, Washington allows only one, and all states require review and prior approval.

There were no examples in the states visited of different approaches to the purchases of hearing aids. Three states, California, Connecticut, and Washington, did express interest in volume purchases, but none have a fully developed plan for such a program. The Veterans Administration, of course, provides the model for such programs. Not only does it have a highly regarded system for assuring the quality of the hearing aids it provides, it also achieves a very reasonable price for these aids. Both of these are extremely relevant to Medicaid reimbursement for hearing aids.

Beyond the activities of the VA and the associated programs run by the Department of Defense virtually no private program offers any useful guidance for reimbursement.

The next section deals with alternative reimbursement policies based on the findings and the information developed in Section 2.

4. *RECOMMENDATIONS*

This paper has discussed the means by which hearing aids are obtained and suggested methods for acquiring aids. It has presented a review of the hearing aid industry as it is currently constituted and the pricing structure of that industry. Next the paper examined the reimbursement techniques of five state Medicaid programs, the Veterans Administration, and several other programs. Recommendations for Medicaid hearing aid reimbursement policies must account for this environment and also address several specific considerations. Among these are:

- any policy suggestion has to conform to legislative and regulatory requirements or suggest valid changes in these requirements;
- suggested policies should not diminish the quality and availability of services, but should, if possible, expand both;
- recommended policy should be easy and inexpensive to administer; and
- recommendations should reinforce the "prudent buyer" provisions of Medicaid laws and regulations.

Based on these general guidelines and the review of the hearing aid industry and various reimbursement policies, the following recommendations are presented:

- Hearing Examinations

  The first point about hearing examinations is that Medicaid requirements should be made explicit on what testing is required. Although those states visited required both a medical and audiological exam, two states did not. There is wide agreement among professional hearing specialists that both a medical and

audiological exam should be carried out prior to the acquisition of a hearing aid. This has several advantages: it assures that any medical problem is addressed; it assures that hearing testing is carried out by competent personnel; and it assures that only those who need a hearing aid get them. As was demonstrated in Section 2 of this report, leaving diagnosis to the hearing aid dealer does not assure appropriate utilization of hearing aids. Medicaid should therefore specifically state that both a medical examination and an audiological test be performed prior to reimbursing for a hearing aid.

In line with this requirement, the structure of reimbursement should be carefully differentiated. By this is meant that there should be specific procedures codes and reimbursement rates for hearing testing related to hearing aids. The most rational approach would be a staged process of procedures that includes:

- an initial medical exam which determines any medical dysfunction in hearing impairment;
- a secondary procedure for audiological tests necessary to fit a hearing aid; and
- a specific follow-up procedure to evaluate the hearing aid's effectiveness.

The motivation behind this proposal is to limit allowable procedures and the fees for them only to those necessary for dispensing hearing aids. Obviously, other acceptable procedures related to

otological and audiological exams can be used in those cases unrelated to hearing aids. Several of the states visited had procedure codes of this sort, and California serves as a model.

The last procedure code suggested, follow-up, is especially important. This reinforces the recipient's motivation to use the aid, and can serve as a check on the fitting done by the hearing aid dealer. The charges for this activity should be kept to a minimum and should be considered as a subpart of the overall testing procedures.

In all cases, fees for hearing aid related testing should be substantially lower than those for comprehensive otological examinations and audiological testing. By so doing, this cost impact on states that do not currently require these examinations can be controlled and unwarranted procedures eliminated.

- Equipment - Recommendations about hearing aid reimbursement policy for Medicaid must address several issues. First there is the high cost associated with hearing aids. Although manufacturers charge only between $80.00 and $140.00 for monaural hearing aids, the cost to consumers and to Medicaid range from $240.00 to $350.00 for those same instruments. Not only are prices high but there is no assurance of the quality of the aid. As pointed out in Section 2, the HEW Task Force on Hearing Aids found "wide variations" in hearing aid performance; and the New York League of the Hard-of-Hearing found that 50% of the aids they tested did not meet manufacturers' specifications. Finally, hearing aid dealers

provide the vast majority of services related to hearing aids as well as the equipment itself. The numbers of otologists, otolaryngologists and audiologists are limited and all are found primarily in major urban and suburban areas.

How do current Medicaid reimbursement policies address these issues? As to prices, state programs have various approaches, none of which appears to control effectively all costs associated with hearing aids. Some states set maximums on total hearing aid cost but do not limit the dealers' fees except within the overall maximum. Conversely, some states limit the dealers' fees but do not control the reimbursement for the equipment. In the former case, the Medicaid program may be paying for a number of services that they do not need. The states of California and Michigan have done studies that indicate average dealer expenses assigned to the sales of a hearing aid are approximately $100.00. These figures allow a number of expenses unrelated to simply supplying the aid. In Medicaid, all the dealer is required to do is order and fit the aid. All testing is done by otologists or audiologists. There is little reason that Medicaid should pay for such things as sales-related expenses and commissions. This is reinforced by the fact that several "discount" hearing aid dealers, include Master Plan Service Company of Minneapolis, sell hearing aids for 40 to 50% less than retail prices. Thus, while hearing aid dealers and state studies based on surveys of dealers rationalize a price per aid, including expenses and profit, very close to the manufacturers' suggested retail price, there are respectable suppliers

that cut their prices by half. This is because these discount dealers do not supply or charge for anything but ordering and fitting the aid. In general, they do no extensive selling and require a prescription from an otologist or audiologist before they will supply an aid. These suppliers, therefore provide the exact services required for a Medicaid patient at considerably reduced costs, again suggesting that dealer fees now allowed by Medicaid can be well defined and tightly controlled.

As suggested, some states do limit the dealers' fee but do not limit the price of the aid dispensed. This means that a hearing aid dealer can supply and charge for a higher priced aid when a cheaper model would suffice. Overall maximums on reimbursement do not necessarily control this situation because they are set high enough to account for a number of kinds of aids. It is possible then to supply a medium power, in-the-ear aid with a high suggested retail price, when other, less expensive models could fit the need, because the maximum does not differentiate among specific types of aids.

Coupled with the questions about what the price of a hearing aid should be and how much a dealer should charge is the question of quality. No Medicaid program reviewed has any method of assuring instrument quality, even if reference is made to some set of standards such as ANSI. The only requirement in this area is that a one year guarantee on parts and workmanship accompany the aid. Without such controls, repair charges can increase, and of course, the recipient does not receive appropriate correction.

Questions about accessibility and availability of aids will be considered in the following discussion about how reimbursement policy should be developed.

To bring about a more valid method of reimbursement for hearing aids, the following recommendations appear appropriate:
First, the price of the equipment should be separated from the dealer fee; both should be determined separately. The dealer fee should be determined based on the actual expenses incurred by the dealer in supplying the aid to a Medicaid recipient, not on what the dealers' costs are in supplying the general public. At the same time these fees must be generous enough to assure participation in the program. While a determination of the dealer costs is outside the scope of this paper, the actual expenses incurred by dealers in supplying Medicaid patients is certainly in a range around the $100.00 figure developed by the California and Michigan surveys. Connecticut has proposed a fee of $125.00, which seems generous, given rising costs since the state cost survey and allowing for dealer profit.

The questions of equipment cost and quality can be tied together. It is recommended that states limit the number of hearing aids that they will reimburse for to those with better than average performance scores in the VA tests. These aids would be assigned maximum reimbursement based on manufacturers suggested wholesale prices. Furthermore, reimbursement could be limited only to those in each category of hearing aids that have both high performance

test scores and low prices, that is, the most cost-effective aids. This can be determined by dividing the price by the VA performance score to determine the lowest cost per point of quality. This is one primary method used by the VA in its hearing aid purchases.

To accomplish this states would have to do several things. They would have to determine first the kinds and quantities of hearing aids dispensed to Medicaid recipients. This would establish the categories of aids, just as the VA specifies the seven kinds of aids it purchases. Next, for each category of aids, e.g., "mild behind-the-ear models," a state would rank the aids for cost effectiveness, based on the VA's annual "Handbook of Hearing Aid Measurement" or other valid sources, thus making a preliminary selection of approved aids. The states would then survey the supply of models in each category in the state. It may be necessary to adjust the approved list to assure a sufficient supply of each category of aids.

This approach to reimbursement should assure the quality of aids dispensed and limit the costs of hearing aids by setting specific maximums on equipment, by reimbursing only for specific cost-effective aids, and by limiting fees to dealers.

Nevertheless, there are drawbacks to this, mainly centered on availability and accessibility. Dealers who do not sell any of the approved aids would be eliminated as suppliers. Other dealers may choose not to participate, given these controls or manufacturer

pressure. Recipients may have to travel to obtain the specific aid prescribed or may not know where to go to obtain their aid. All of these are problems, but none is insurmountable. A loss of dealers may require some adjustments in the approved list of aids. Travel by recipients seems a very secondary problem because recipients may already have to travel to obtain diagnostic examinations, and it seems reasonable to assume that where there are audiologists and otologists there are dealers or dispensing audiologists. The question of finding the right supplier for the aid prescribed can be solved by simply giving the recipient a list of appropriate suppliers for the aid. The recipient can choose among these, thus not limiting "freedom of choice." Such lists could be derived directly from the survey performed by the state on hearing aid model availability.

This system has several advantages over current reimbursement policies. It directly controls dealer fees, limiting them to only reasonable charges for services rendered. It sets a specific maximum cost for each hearing aid. It guarantees that only high quality aids with reasonable prices will be dispensed. Although it may to some degree hinder availability, it does not hinder "freedom of choice." While the initial study work and surveys may incur some costs, administration will not be affected, except for the need to update lists of approved aids and to indicate where they may be obtained. In sum, this system should save money and assure better quality equipment for recipients.

There is one other possible advantage, given the interest of certain states in some form of direct purchase of hearing aids from manufacturers. The system can be used as a basis for this more ambitious policy. Essentially the whole system could remain in place. Instead of the dealer or dispensing audiologist paying the manufacturer for the aid and then being reimbursed by the state, the state would pay the manufacturer for the aid. The effectiveness of this approach depends on whether the state can achieve a price lower than that charged by dispensers. This could be determined by asking for bids directly from manufacturers for specified aids supplied on an "as needed" basis. The state could, of course, supply the manufacturers with an approximate number of purchases over time. Several states have considered this policy and the VA now uses it; it has not however been tested in practice. It can only be recommended therefore, that such an approach be given further analysis and consideration.

APPENDICES

GLOSSARY

ACO - American College of Otolaryngology (ACO). The national organization that represents physicians who specialize in care of the ear, nose, pharynx, and larynx.

ASHA - American Speech and Hearing Association (ASHA). The national organization that represents audiologists (defined below).

Air conduction test - hearing loss measured by placing earphones over the ear and measuring the entire hearing mechanism.

Apalsia - malformation of the inner ear.

Atresia - absence or malformation of the outer or middle ear.

Audiogram - a graphic description of a person's hearing.

Audiologist - a specialist in the non-medical evaluation and rehabilitation of persons with hearing disorders. He generally has an M.A. or a Ph.D. degree.

Bilateral - two ears.

Binaural - use of two ears or two hearing aids.

Bone conduction test - hearing loss measured by placing a vibrator on the mastoid process (behind the external ear) and measuring the auditory nerve.

Cochlea - the winding cavity within the inner ear, shaped like a snail shell, containing the end-organ of hearing which finally changes the pressure waves of sound into nerve impulses.

Conductive hearing loss - a hearing loss caused by damage to the outer or middle ear.

Decibel - a unit for expressing the relative intensity of sounds or a scale from zero from the average least perceptible sound to about 130 for the average pain level.

Ear mold - a device which fits into the ear canal to which a hearing aid is attached. It is made individually for each person.

Functional hearing loss - a hearing loss that is not caused by an organic condition.

Hearing aid - a device which amplifies sound. There are basically four types of hearing aids. A hearing aid may be post auricular (ear level) which fits behind the ear. It may be "all-in-the-ear" which fits directly into the ear canal, a body aid which is worn in a pocket on the chest with a cord going to the ear, or an eyeglass aid which is connected to the eyeglass.

Hearing aid dealer - an individual trained to select, adapt, and fit hearing aids, and to provide continuing service on the use of the aid. He may also offer hearing tests as part of the hearing aid fitting procedures.

Hearing clinician - the person who is trained to evaluate, diagnose and treat children and adults with hearing problems.

Hertz - a unit of frequency equal to one cycle per second.

Impedance testing - a method of evaluating the functioning of the middle ear.

Middle ear - portion of the hearing mechanism between the outer ear and the cochlea. Consists of the eardrum, the ossicles (bones), the opening of the eustachian tube, the oval window and the round window.

Monaural - use of one ear or one hearing aid.

NHAS - National Hearing Aid Society (NHAS). The national organization that represents and provide home-study training to hearing aid dealers.

Organic, - a hearing loss caused by a physical condition.

Otolaryngolist - an M.D. or D.O. who specializes in care of the nose and throat as well as the ear.

Otologist - a specialist in diagnosis and treatment of the ear. He has a Doctor of Medicine (M.D.) or a Doctor of Ostepathy (D.O.) degree.

Residual hearing - the hearing which remains after hearing loss.

Sensori-neural hearing loss - a hearing loss caused by damage to the cochlea, eighth auditory nerve or auditory pathways.

Speech and hearing clinician - the person who is trained and certified to evaluate, diagnose and treat speech and language and communication problems.

Unilateral - in one ear.

BIBLIOGRAPHY

1. Commerce Clearinghouse, Incorporated, Medicare and Medicaid Guide, Chicago, 1974, 1975, 1976, 1977.

2. Consummer Reports, "How to Buy a Hearing Aid," Washington, June 1976.

3. Lee , Lyndon E., Jr., Statement before Subcommittee on Government Regulations of the Small Small Business Committee, May 22, 1975.

4. Maryland Center for Public Broadcasting, "Consumer Survival Kit - Ears to Ya," Owings Mill, Maryland, February 1976.

5. National Hearing Aid Society, The Elimination of The Hearing Aid Specialist, Livonia, Missouri, March 1975.

6. Public Citizen's Retired Professional Action Group, Paying Through The Ear: A Report on Hearing Health Care Problems, Washington, October 1973.

7. Spahr, Frederick T, and McLauchlin, Robert M., representing the American Speech and Hearing Association before the U.S., Food and Drug Administration, in the Matter of "Proposed Professional and Patient Labelling Requirements and Conditions of Sale for Hearing Aid Devices," Docket No. 764-0019, "Comment," 1976.

8. U.S. Congress House, Subcommittee on Health and Long-Term Care of the Select Committee on Aging, Report, Medical Appliances and the Elderly: Unmet Needs and Excessive Costs for Eyeglasses, Hearing Aids, Dentures and Other Devices, 44th Congress, 2nd Session, September 1976.

9. _____, Hearings, Medical Appliances for the Elderly: Needs and Costs., 94th Congress, 2nd Session, June 23 and 24, 1976.

10. U.S. Congress, Senate, Subcommittee on Consumer Interests of the Elderly of the Special Committee on Aging, Hearings, Hearing Aids and Older Americans, 93rd Congress, 1st Session, September 10, 1973.

11. U.S., Congress, Senate, Subcommittee on Government Regulation of the Select Committee on Small Business, Hearings, Problems of the Hearing Aid Industry, 94th Congress, 1st Session, May 20, 21 and 22, 1975.

12. U.S. Departmenet of Commerce, Facts About Hearing and Hearing Aids, A Consumer's Guide from the National Bureau of Standards, NBS, CIS 4, November, 1971.

13. U.S. Department of HEW, Interdepartmental Task Force on Hearing Aids, Final Report to the Secretary on Hearing Aid Health Care, July, 1975.

14. U.S. Department of HEW, National Center for Health Statistics, Persons with Impaired Hearing, United States - 1971, DHEW Publication No. (HRA) 76-1520, November, 1975.

15. U.S., United States of America before Federal Trade Commission, Initial Decision, Docket No. 8928, Beltone Electronics Corporation, et al., September 2, 1976.

16. U.S., Veterans Administration Marketing Division, "Hearing Aids, Standards Models, in Quantities as may be Required During the Period October 1, 1977 through September 30, 1979", Solicitation No. M3-Q1-78, Hines, Illinois, November 16, 1976.

TUESDAY, FEBRUARY 15, 1977
PART IV

federal register

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

HEARING AID DEVICES

Professional and Patient Labeling and Conditions For Sale

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER H—MEDICAL DEVICES

[Docket No. 76N-0019]

PART 801—HEARING AID DEVICES

Professional and Patent Labeling and Conditions for Sale

The Food and Drug Administration (FDA) is establishing uniform professional and patient labeling requirements and conditions for sale of hearing aid devices. The regulations prescribe the types of information that must be included in the labeling to provide hearing health professionals and patients with adequate directions for the safe and effective use of a hearing aid; specify the technical performance data that must be included in the labeling to ensure that hearing health professionals have adequate information to select, fit, and repair a hearing aid for a patient; and restrict the sale of a hearing aid to those patients who have undergone medical evaluation within the past 6 months, but with a provision that fully informed adult patients (18 years of age or older) may waive the medical evaluation because of personal or religious beliefs. These regulations shall become effective August 15, 1977.

In the FEDERAL REGISTER of April 21, 1976 (41 FR 16756), the Commissioner of Food and Drugs proposed to amend Chapter I of Title 21 of the Code of Federal Regulations by adding new §§ 801.420 and 801.421 to establish professional and patient labeling and conditions for sale for hearing aid devices, referred to hereinafter as hearing aids. Interested persons were given until June 21, 1976 to submit written comments, suggestions or objections. Approximately 500 comments were received from consumers, consumer groups, hearing aid dispensers, trade associations, manufacturers, audiologists, physicians, and government agencies.

The following text contains pertinent background information and a summary of the comments received on the proposal, as well as the Commissioner's evaluation of and response to the comments:

The preamble to the proposed regulation contained a section entitled "Background," which summarized the activities of consumer groups, Congress, and the Department of Health, Education, and Welfare (HEW) that have identified problems in the present hearing aid health delivery system. The "Background" section in the proposal failed, however, to reference the efforts of two Congressional committees that held open hearings on the hearing aid health care delivery system. In May of 1975, the Subcommittee on Government Regulations of the Select Committee on Small Business, United States Senate, chaired by Senator Thomas J. McIntyre, held hearings on economic problems in the hearing aid industry (Ref. 14). The subcommittee investigated matters such as competition, prices, advertising and marketing practices, research and development, government purchasing and reimbursement, the role of small business, and in general, how the hearing aid industry has responded to the needs of the hearing impaired. In April of 1976 the Senate Permanent Subcommittee on Investigations, chaired by Senator Charles H. Percy, also held hearings on the hearing aid industry. These hearings reconfirmed that many hearing-impaired consumers do not obtain a medical evaluation of their hearing impairment before purchasing a hearing aid. Senator Percy, in closing the hearings, stated that "Twenty million hearing-impaired Americans are being denied top-flight treatment by a delivery system that simply is not working" (Ref. 15). As a result of testimony presented at these hearings, Senator Percy recommended that FDA promulgate regulations that would restrict the sale of hearing aids to those patients who have undergone a medical evaluation.

FEDERAL TRADE COMMISSION ACTIVITIES AFFECTING THE HEARING AID INDUSTRY

The Federal Trade Commission (FTC) also has been studying the hearing aid health care delivery system to determine what steps should be taken to protect consumers from unfair or deceptive acts or practices in the sale of hearing aids. In the FEDERAL REGISTER of June 24, 1975 (40 FR 26646), the FTC published an "initial notice" of a proposed trade regulation rule for the hearing aid industry. The rule making record was closed on October 22, 1976. The reports of the presiding officer and the FTC staff concerning the proposed rule are now being prepared.

The essential provisions of the FTC proposed rule are: (1) A requirement that every hearing aid buyer (with certain exceptions) be given the right to cancel the purchase for any reason any time within 30 calendar days of delivery and receive a refund of most of the purchase price (in effect, a mandatory trial rental period); (2) a requirement that sellers of hearing aids obtain prior express written consent to a sales visit in the buyer's home or office; (3) a prohibition of certain other selling techniques; (4) a prohibition of certain representations concerning hearing aid sellers; (5) a prohibition of certain representations concerning hearing aids; and (6) requirements that certain advertising representations be qualified.

Subsequent to the publication of the FTC proposed rule, the Medical Device Amendments of 1976 (Pub. L. 94-295) became law on May 28, 1976. The Amendments added new paragraph (r) to section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(r)), which provides that a restricted device will be deemed to be misbranded unless all advertisements and other descriptive matter with respect to it (1) bear the device's established name, (2) include a brief statement of the intended uses of the device, relevant warnings, precautions, side effects, and contraindications, and (3) in instances in which it is necessary to protect the public health, include a description of the components of the device or its formula. Section 502(r) further provides that an advertisement for a restricted device shall not, with respect to matters covered by section 502(r) or covered by regulations issued under that section, be subject to the provisions of sections 12 through 15 of the Federal Trade Commission Act (15 U.S.C. 52 through 55), as that act relates to the dissemination of false advertisements for devices. (Section 502(r) of the act closely parallels section 502(n) of the act (21 U.S.C. 352(n)), relating to prescription drugs.)

Section 502(r) gives FDA jurisdiction for regulating certain specified advertising of restricted devices, and the section concurrently removes FTC authority to apply the sanctions of court injunction or criminal penalties under sections 12 through 15 of the Federal Trade Commission Act to prevent these acts. It is the Commissioner's opinion, however, that section 502(r) limits FTC authority only to the extent specifically stated in the section, i.e., section 502(r) applies only to restricted devices and only to possible FTC use of court injunctions or criminal penalties to prevent false advertising relating to the items of information specified in section 502(r). Moreover, section 502(r) does not extend to, or in any way limit, any other authority of FTC related to the regulation of the sale of devices, such as the authority provided to FTC under section 5 of the Federal Trade Commission Act (5 U.S.C. 45) to prevent unfair or deceptive acts or practices.

In sum, it is the Commissioner's opinion that the net effect of section 502(r), as of the comparable provision under section 502(n) relating to prescription drugs, is to enable each agency to approach the regulation of restricted devices from the perspective of its particular statutory mandate. It is also the Commissioner's belief that both agencies will continue, as they have in the past, to work together in pursuit of their separate but closely related mandates. The Food and Drug Administration has long been aware of the FTC activities in the regulation of hearing aids that led to the FTC proposed rule, and the Commissioner believes these activities complement, rather than conflict with, this FDA regulation relating to labeling and conditions of sale of hearing aids. The Commissioner generally supports the FTC proposed rule and believes that the matters addressed therein are particularly within the FTC statutory mandate and expertise.

GENERAL COMMENTS ON THE PROPOSED REGULATIONS

Many comments on the proposed regulations asserted that the proposal did not adequately deal with several major concerns about the present hearing aid health care delivery system. The inadequacy or absence of State licensing laws in requiring minimum competency standards for persons who dispense hearing aids was often mentioned in the comments.

The Commissioner recognizes that the professional and patient labeling regulations and restrictions on the sale of hearing aids are only a partial solution to the problems in the hearing aid health care delivery system, and that these regulations do not address the adequacy of existing State licensing laws that control the dispensing of hearing aids. The Commissioner notes also that the hearings before the Senate Permanent Subcommittee on Investigations of the Hearing Aid Industry (Ref. 15) produced testimony that the competency and training of hearing health professionals, whether physicians, audiologists, or hearing aid dispensers, was of utmost importance to the delivery of quality hearing aid health care services. The Commissioner notes, however, that the Federal Food, Drug, and Cosmetic Act regulates the safety, effectiveness, and labeling of the hearing aid itself. State and local licensing laws, as administered by State and local agencies, are the appropriate legal mechanisms for establishing minimum competency standards for the practice of a health profession or related activity. A major purpose of such licensing laws is to establish standards for the various activities within their purview and to exclude from activities those persons who will not, or cannot, conform to these standards. Such licensing statutes thereby protect the public against unfit and inept practitioners in the health professions and other occupations affecting the public health and safety.

The Commissioner is aware of the efforts of the American Speech and Hearing Association, the National Hearing Aid Society, and other professional organizations to develop minimum competency standards for testing hearing loss for the purpose of selecting and fitting hearing aids. These programs often lead to certificates of competency from the sponsoring organization and often require participation in a continuing education program to maintain the certificates of competency. A shortcoming of such an approach is that these certification programs apply only to the members of the organization. Where State licensing laws are weak or nonexistent, a person dispensing hearing aids can ignore the certification program by not participating in the professional association.

The Commissioner therefore believes that strong State and local licensing laws are needed to establish and maintain minimum competency requirements for those persons who test for hearing loss and select and fit hearing aids. The Commissioner notes, however, that the establishment of such licensing laws is primarily the responsibility of State and local officials.

There were many comments that the proposed regulations provided no relief from the high cost of hearing aids. Moreover, many comments expressed concern that the regulations would add to the cost of hearing aids. The Commissioner notes also that both the Senate hearings and the HEW Intradepartmental Task Force produced testimony that suggested that many elderly Americans do not have hearing aids because of their high cost.

Although FDA does not have any direct control over the price of hearing aids, the Commissioner recognizes that ill-conceived and unnecessary regulations could cause the price of hearing aids to rise, thus creating an additional barrier to the receipt of quality hearing aid health care services. For this reason, FDA has judiciously exercised its rulemaking authority to provide for minimal Federal intervention consistent with essential protection of the public health in the delivery of hearing aid health care services. This approach recognizes the limitations of FDA statutory authority in dealing with such factors as the cost of a hearing aid and the inadequacy or absence of State licensing laws.

The Commissioner also recognizes that personal motivation often plays a major role in determining whether a person who has a hearing impairment will seek assistance. Information collected by the HEW Intradepartmental Task Force on Hearing Aids indicates that an estimated 10 million hearing-impaired persons have not received medical attention to assess their hearing loss and to determine what steps, if any, can be taken to improve their hearing (Ref. 4). The Commissioner believes that it is of paramount importance that any FDA regulations intended to protect the health and safety of the hearing impaired be positive in orientation and not create unnecessary economic or psychological barriers to the receipt of quality hearing aid health care. For these reasons, the FDA regulations have been developed in full awareness of the FTC proposed trade regulation rule for the hearing aid industry, and duplication of effort has been avoided.

A section in the preamble to the FDA proposed regulations entitled "Hearing Health Care Team" drew many comments from audiologists. In general, the audiologists objected to wording in this section, which identified hearing aid specialists or dealers (hearing aid dispensers) as hearing health professionals and legitimate members of the hearing health care team. Many audiologists stated that it was inaccurate to recognize hearing aid dispensing as a profession because many hearing aid dispensers have little academic training.

The Commissioner rejects the contention that hearing aid dispensers should not be included in a characterization of the hearing health care team. The various services provided by hearing aid dispensers, such as testing hearing for selecting and fitting hearing aids, motivating prospective users to try amplification, making impressions for ear molds, selecting and fitting hearing aids, counseling hearing-impaired persons on adapting to a hearing aid, and repairing damaged hearing aids are regarded by many of the hearing impaired as indispensable to their welfare. Many hearing aid users wrote to FDA supporting this position. Many hearing aid users emphasized that hearing aid dispensers were readily accessible for essential services such as repair work. Great importance was attached to the fact that the hearing aid dispenser operated from a place of business that was near to the hearing aid user and also that hearing aid dispensers typically did not require an appointment for services.

The Commissioner recognizes that the accessibility of hearing aid services is of great importance to the quality of hearing aid health care services. The hearing aid dispenser is the most accessible member of the hearing aid health care team, and the hearing aid dispenser sees the hearing-impaired person with greater frequency than either the physician or the audiologist. For these reasons the Commissioner regards the hearing aid dispenser as an important member of the hearing health care team, strategically positioned within the delivery system to provide the hearing aid user with essential services.

The Commissioner has concluded, however, that necessary improvements in the quality of hearing aid health care services depend largely on hearing aid dispensers recognizing their obligation to achieve greater competency in testing hearing in order properly to select and fit a hearing aid. Although many hearing aid dispensers already have obtained specialized training in hearing aid evaluation from hearing aid manufacturers and have completed formal academic programs in the selection and fitting of hearing aids, other hearing aid dispensers need additional training.

The Commissioner sees no value in characterizing hearing aid dispensers solely as "sales persons," or in minimizing the importance of "selling" as it relates to motivating persons to try amplification. Often a person with a hearing impairment lacks the motivation to try a hearing aid or believes a social stigma is attached to wearing a hearing aid (Ref. 4). Although there are a number of documented cases of excessive and abusive sales practices, this is not to say that some selling practices and techniques such as a trial-rental or purchase-option plan, which strengthen motivation to try a hearing aid, are inherently bad. When the number of hearing-impaired persons who currently wear hearing aids is contrasted with the number of people in the United States with a hearing impairment who could be helped by a hearing aid, it is clear that many people are reluctant to acknowledge their hearing impairment or to seek assistance. Ethical selling practices that provide the potential hearing aid user with incentives to try a hearing aid are therefore to be encouraged.

A majority of the comments addressed the medical evaluation provision of the proposed regulation, which required as a condition of sale that a person with hearing impairment obtain a medical evaluation from a physician, preferably an ear specialist, before buying a hearing aid.

The Commissioner has concluded, after consideration of these comments, that good hearing health care practice requires that persons with hearing loss have a medical evaluation by a licensed physician (preferably a physician who spe-

specializes in diseases of the ear) prior to the purchase of a hearing aid. The medical evaluation by the physician is necessary in determining the cause of, and the pathology associated with, the patient's hearing loss. Such a medical evaluation often includes an interpretation of a medical history, a physical examination, laboratory studies, X-ray studies, and, in some instances, a hearing test.

The Commissioner agrees with the American Council of Otolaryngology and other physicians who commented that the recognition of an organic cause for hearing impairment is of extreme importance to the health and safety of the hearing-impaired patient. The American Council of Otolaryngology pointed out that some of the causes for sensorineural hearing loss include conditions such as brain tumor, syphilis, endocrine disorder, collagen diseases, and endolymphatic hydrops. Accordingly, the final regulation continues to require as a condition for sale, that a person, as a general rule, have obtained a medical evaluation from a licensed physician within the preceding 6 months before he is sold a hearing aid. The Commissioner has determined that the medical evaluation is necessary to protect the health and safety of hearing-impaired patients because patients, audiologists, and hearing aid dispensers are unable to differentiate, diagnose, evaluate, and treat the medical cause or causes of a hearing impairment.

The Commissioner emphasizes, however, that the primary health concern underlying the medical evaluation requirement is not immediately related to any direct risk to a user from the hearing aid itself; rather, the medical evaluation requirement is based upon the recognition that an unnecessary or partially effective hearing aid device may be substituted for primary medical or surgical treatment, thus depriving the hearing-impaired patient of benefit of appropriate medical diagnosis and care and resulting in a detriment to health. In addition to delaying proper medical diagnosis and possibly reducing the efficacy of the correct treatment, purchase of a hearing aid device that may not achieve its intended effect involves a high and unnecessary cost to the patient.

A number of comments indicated that there is some confusion about the purpose of the medical evaluation requirement in the proposed regulation. Simply stated, the purpose of the medical evaluation by a licensed physician is to assure that all medically treatable conditions that may affect hearing are accurately identified and properly treated before a hearing aid is bought. It should be emphasized that the medical evaluation requirement does not require the physician to prescribe, recommend, or certify that a patient may be helped by a hearing aid. The provision simply requires that the physician provide the patient with a written statement indicating that the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid.

The Commissioner notes that a hearing aid device is not an inherently dangerous device and that the number of persons who will in fact require a medical or surgical treatment is relatively small in comparison to the number of individuals who may benefit from amplification. For this reason, FDA has attempted to design the medical evaluation requirement to reflect the practical and logistical problems of medical evaluation, the availability of licensed physicians, the mobility of the hearing impaired, and the personal and religious beliefs of those persons who refuse to consult with physicians.

Several consumers wrote that since the hearing impaired patient is paying for the hearing aid and subsequent services, any medical evaluation requirement is ultimately an infringement of individual rights. These persons emphasized that currently it is a personal decision whether or not to see a physician. Other consumers objected to a medical evaluation on the basis of philosophical and political grounds, expressing the preference for freedom of choice. Other consumers indicated that a mandatory medical evaluation requirement would impose serious hardships in obtaining the services of a physician, particularly an ear specialist. The National Hearing Aid Society and a number of consumers felt that the medical evaluation requirement should be mandatory only before the fitting of the first hearing aid. They contended that this approach would assure adequate attention to the medical needs of the hearing-impaired person while promoting convenience, economy, and efficiency in the hearing aid health care delivery system.

In view of these comments, the Commissioner has concluded that the final regulation should contain provisions that would enable a fully informed adult to waive the medical evaluation. But, because the Commissioner believes that the exercise of such a waiver of medical evaluation is not in the best health interest of the patient, the opportunity for waiver is limited to fully informed adult patients. The final regulation prohibits any hearing aid dispenser from actively encouraging a prospective user to waive a medical evaluation.

Under proposed § 801.421(a)(3) a waiver of the medical evaluation would not have been permitted where it was evident to the dispenser after inquiry, actual observation, and review of any available information concerning the prospective user, that the prospective hearing aid user had any of seven designated otologic conditions at the time of sale. Because these otologic conditions may indicate that the hearing loss is symptomatic of a more serious medical dysfunction, and that other treatment is needed, the proposed regulation would have prohibited a dispenser from selling a hearing aid to a prospective user if any of these otologic conditions were evident.

The Commissioner is concerned that a hearing aid user would interpret the absence of these seven designated otologic conditions as a justifiable reason for ignoring the required medical evaluation. The Commissioner is also concerned that undue importance has been attached to the seven designated otologic conditions by incorporating these conditions into the waiver provision. In the proposed regulation, the seven designated otologic conditions were to serve as screening criteria for the hearing aid dispenser to use in determining whether the prospective hearing aid user could exercise the waiver to the medical evaluation requirement. The Commissioner has concluded that the health interest of the prospective user would be best served by obtaining a medical evaluation from a licensed physician before purchasing a hearing aid. A prospective user should not be misled into thinking that the absence of any of the seven otologic conditions indicates that there is no need to obtain a medical evaluation.

The Commissioner believes, however, that the designated otologic conditions continue to serve as useful warning signals or "red flags." Accordingly, reference to the presence of any of the designated otologic conditions has been moved to a new section of the User Instructional Brochure, entitled "Warning to Hearing Aid Dispenser." This new provision requires a hearing aid dispenser to advise a prospective hearing aid user to consult promptly with a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid if the hearing aid dispenser determines through inquiry, actual observation, or review of any other available information, that the prospective user has any of the designated otologic conditions. The complete text of the "Warning to Hearing Aid Dispenser" is also required to appear in the User Instructional Brochure to inform prospective users, as well as the dispenser, of the necessity to consult a physician if any of the designated otologic conditions are evident.

The American Speech and Hearing Association and many audiologists commented that a mandatory audiological evaluation by an audiologist should be required by Federal regulation as a condition for sale of a hearing aid. Comments on the proposed regulation expressed a wide diversity of opinion as to the reliability of audiological testing in predicting to a certainty whether or not a patient may benefit from a hearing aid. The American Council of Otolaryngology (ACO) stated that it was unable to find evidence to support the contention that audiological testing procedures will predict a patient's acceptance of a hearing aid device. It was pointed out by ACO that the terms "acceptance, benefit and satisfaction" when applied to hearing aids often involved a subjective response by the patient.

After reviewing all the conflicting information in the public record regarding the predictive value of audiological testing in determining whether or not a patient will benefit from a hearing aid, the Commissioner has concluded that a requirement that a patient obtain certain

mandatory audiological tests from an audiologist is not appropriate at this time. The Commissioner has concluded that the record does not justify requiring mandatory audiological evaluation to determine hearing aid candidacy or patient benefit from the use of amplification. Mandatory audiological evaluation would create an additional barrier to the receipt of a hearing aid device in those areas of the country where audiological services are scarce. Such a requirement also would increase the cost of obtaining a hearing aid without providing any conclusive assurance that the patient would benefit from amplification.

Because of the difficulty of determining in advance whether an individual will benefit from a hearing aid, FDA supports the requirement of a trial-rental or purchase option plan embodied in the FTC proposed rule, which will afford every prospective hearing aid user the opportunity to wear the selected hearing aid in a variety of uses during which the hearing-impaired user can make an informed judgment on whether a benefit is obtained from the use of amplification. The Commissioner believes that in the final analysis the hearing aid user is the person best qualified to determine whether or not a hearing aid is useful and efficacious for its intended purpose. A trial-rental option is better than mandatory audiological tests in determining patient benefit from amplification.

The Commissioner is aware that the FTC proposed rule requiring a mandatory trial-rental period will not be promulgated for some time. But the National Hearing Aid Society and several hearing aid manufacturers have adopted voluntary trial-rental or purchase-option programs for prospective hearing aid users. The Commissioner believes that these voluntary actions are important enough to the welfare of the hearing impaired to require that the User Instructional Brochure contain information advising prospective hearing aid users to inquire about the availability of a trial-rental or purchase-option program. In addition to helping to assure that the selected aid or aids will be beneficial, such a requirement will encourage hearing aid use among those prospective hearing aid users who lack the motivation to try a hearing aid because of the fear that they will spend a great deal of money with no guarantee of benefit.

Although the final regulation does not require a mandatory audiological evaluation as a condition for sale of a hearing aid, the Commissioner recognizes that the audiologist is an important member of the hearing health care team, qualified by academic and clinical training to assist in the prevention, identification, evaluation, and rehabilitation of persons with auditory disorders that impede or prevent the reception and perception of speech and other acoustic signals. In addition to basic audiometric evaluation, audiologists may provide hearing aid orientation, auditory training, speech reading, speech conservation, language development, and counseling and guidance services. The audiologist often provides health related services to children and adults with such identifiable disorders as receptive and/or expressive language impairment, stuttering, chronic voice disorders, and serious articulation problems affecting social, emotional and vocational achievement, and speech and language disorders accompanying conditions of hearing loss, cleft palate, cerebral palsy, mental retardation, emotional disturbance, multiple handicapping conditions, and other sensory and health impairments.

Because hearing loss may impede or prevent the reception and perception of speech and other acoustic signals, the Commissioner is requiring that the User Instructional Brochure contain advice that a child with a hearing loss should be directed to an audiologist for evaluation and rehabilitation. The Commissioner expects that the physician, in conducting the medical evaluation of a patient, will determine whether the patient's hearing loss or speech impairment will require the consultation of an audiologist. Notwithstanding this fact, the Commissioner has concluded that the User Instructional Brochure should contain special reference to the need for audiological consultation when the person experiencing the hearing impairment is a child.

Responses to Specific Comments

1. Three comments suggested that in the definition of "hearing aid" the word "designated" should be changed to "designed" so as to conform to the definition in the regulations proposed by FTC.

The Commissioner agrees with these comments and the change is made. The Commissioner notes that the definition for "hearing aid" as used in the regulation, includes over-the-ear, in-the-ear, eyeglass, and on-the-body type air-conduction hearing aids.

One comment noted that group auditory trainers, defined as a group amplification system purchased by a qualified school or institution for the purpose of communicating with or educating individuals with hearing impairments, would fall under the definition of "hearing aid" as used in the proposal. The comment further noted that it would be inappropriate to apply the proposed conditions for sale for hearing aid devices to group auditory trainers.

The Commissioner agrees with this comment and a change is made in the regulation so that the normal conditions for sale requirements do not apply to this special type of hearing aid.

2. Ten comments suggested that the definition of "seller" should be changed to indicate clearly that it applies to anyone who dispenses a hearing aid to a member of the consuming public. These comments pointed out that in addition to the hearing aid dealer, many physicians and audiologists dispense hearing aids.

The Commissioner agrees with these comments. The regulations are necessary to protect the consumer regardless of who dispenses the hearing aid device. The term "seller" is therefore changed to "dispenser" wherever appropriate in the regulation.

3. Two comments said that "sale" or "purchase" should not be applied to the lease or rental of a hearing aid because such transactions are substantially different from a sale or purchase in that the title to the hearing aid device remains with the lessor.

Although "sale" or "purchase" and "lease" or "rental" may be substantially different terms in business and legal effect, the Commissioner has determined that they should be treated in the same manner for the purposes of this regulation. Medical evaluation, the User Instructional Brochure, and the required notices to the prospective purchaser are all equally necessary to protect the consumer whether the transaction is in the form of a sale or lease or rental. Accordingly, these comments are rejected.

4. Seven comments suggested that "otolaryngologist" (ear specialist) and "audiologist" should be definited to clarify their roles in the hearing aid delivery system.

The Commissioner agrees with these comments and definitions of "audiologist" and "ear specialist" have been included in the regulation.

5. One comment suggested that the term "used hearing aid" should be defined, since the hearing aid dispenser must designate a "used hearing aid" as such. This comment pointed out that it may not be clear at what point a hearing aid becomes a "used hearing aid."

The Commissioner agrees with this comment and defines "used hearing aid" in the final regulation. The FTC proposed rule also requires that a "used hearing aid" be designated as such. The Commissioner believes that there should be conformity in this area and is adopting the definition included in the FTC proposed rule.

6. Various comments addressed the proposed labeling required to be placed on the hearing aid device, which included the name of the manufacturer or distributor, the model name, the serial number, and the month and year of manufacture. Five comments suggested that the information required would not fit on some of the smaller hearing aid units. Eight comments noted that the year of manufacture is irrelevant in that hearing aid models are not changed every year and therefore the fact that a hearing aid was manufactured in a previous year does not indicate that it is not the latest model. One of these comments further noted that the month of manufacture is certainly irrelevant. Four comments suggested that including the month and year of manufacture on hearing aids would cause inventory problems for manufacturers and dispensers because dispensers would be unwilling to order in advance, fearing that the hearing aids would remain on their shelves for some time and that customers would consider them outdated.

The preamble to the proposed regulation stated that this information was required to be placed on hearing aids for several reasons: To assure that the hear-

ing aid is adequately identified for quality control and repair, to identify the hearing aid in the event that a product defect warrants recall of the device, and to protect prospective users from false and misleading claims concerning the newness of the device. The Commissioner believes that these reasons are still persuasive, but he does believe that some adjustments can be made to mitigate some of the problems noted by the comments. The requirement that the model name be marked on the hearing aid is changed to "model name or number." This may ease the problem of including all this information on the smaller hearing aid units. The final regulation is also being changed to require that only the year, and not the month, of manufacture be marked on the hearing aid. Requiring that the month as well as the year of manufacture be marked on the hearing aid adds little to the solution of the problems necessitating this requirement, and omitting the requirement will reduce the amount of information to be included on the smaller hearing aids.

7. About the requirement that hearing aids be marked with a "+" symbol to indicate the positive connection for battery insertion, one comment suggested that FDA should require that all hearing aids be manufactured so that it is physically impossible to insert the battery in the reversed position.

Such a requirement would be of little value to the hearing aid user and would require a major redesign of many hearing aids, thus increasing the cost of hearing aids. The comment is therefore rejected.

8. Five comments said that the requirement that the User Instructional Brochure contain an illustration of the hearing aid adjustments should be modified to require that only user adjustments be illustrated. These comments pointed out that users would otherwise make adjustments which only qualified individuals should make and this would cause unnecessary problems in the use of the aid.

The Commissioner agrees with these comments and the change is made accordingly.

9. Three comments said that it would be very difficult to compile a complete list of suitable replacement batteries for inclusion in the User Instructional Brochure, as required by the proposed regulation, and that it would be better to require only a generic designation of replacement batteries.

The Commissioner agrees with these comments and the change is made.

10. Four comments said it would be impossible to list all repair facilities, as required by the proposed regulation.

The Commissioner agrees that it would be difficult to list all repair facilities and feels that a more general statement is desirable. As a result, the final regulation requires that the User Instructional Brochure contain information regarding how and where to obtain repair service, including a specific address, or addresses, where the user can go or send the hearing aid to have the repair done.

11. Three comments said the requirement that the User Instructional Brochure contain a description of environmental conditions that the hearing aid user may reasonably encounter that could adversely affect the hearing aid is vague.

The Commissioner agrees with these comments and the requirement is rewritten to provide examples of such conditions. The User Instructional Brochure is now required to include only commonly occurring avoidable conditions that could adversely affect or damage the hearing aid.

12. Twenty-nine comments said that the proposal did not include several side effects from hearing aid use that may warrant consulting with a physician, and that should be included in the User Instructional Brochure. These include tinnitus, headaches, dizziness, pain in the ear, acoustic trauma, feeling of blockage, loss of balance, fatigue, additional hearing loss, active drainage, and sudden hearing loss.

The Commissioner believes that such conditions would not be actual side effects from the use of the hearing aid but would be the result of misevaluation of the hearing problem or the result of a medical problem unrelated to the hearing aid itself.

But two comments mentioned that the ear may secrete additional cerumen (ear wax) to protect against the foreign object, i.e., the earmold, and that this would necessitate more frequent cleaning of the cerumen from the ear.

The Commissioner agrees with these comments and is amending the final regulation to include reference to the accelerated accumulation of cerumen as a possible side effect from the use of a hearing aid.

13. Five comments objected to the requirement that the User Instructional Brochure include the statement that infrequent use of a hearing aid usually does not permit the user to attain full benefit from its use. These comments pointed out that, in certain cases, the user should wear the hearing aid only at certain times. For example, a hearing aid user who works in high intensity noise conditions should not use the hearing aid at work. One of these comments said that the required statement would be confusing to such people.

The Commissioner believes that this statement is appropriate in the vast majority of cases and is therefore necessary because many users, to their own detriment, use their hearing aid only part-time. The Commissioner has, however, modified the statement to clarify the fact that it does not apply in all situations. The Commissioner believes that it is the responsibility of hearing aid dispensers to obtain sufficient information from the user regarding his type of employment or other activities to be able to inform him as to whether or not the hearing aid should be worn at all times.

14. Three comments objected to the requirement that the User Instructional Brochure include a statement that the use of a hearing aid is only part of hearing habilitation and that auditory training and instruction in lipreading may also be necessary. These comments noted that the dispenser would inform the user of any need for counseling during the adjustment period.

A hearing aid will not restore normal hearing, nor will a hearing aid always increase the ability of the user to distinguish different sounds. As a result, some hearing aid users become discouraged in the process of adapting to the use of a hearing aid, put the hearing aid aside, and discontinue its use in auditory habilitation.

The HEW Task Force pointed out that the problems resulting from a hearing loss are multidimensional, affecting both the total health and social well-being of the hearing-impaired person, and that there is a need to pursue a comprehensive and vigorous attack on hearing problems. Many people with hearing problems are not aware of the necessity and availability of auditory training and instruction in lipreading. The Commissioner has, therefore, determined that this statement should be retained in the User Instructional Brochure.

15. Five comments suggested that the manufacturer should not be required to include technical data relating to the hearing aid in the User Instructional Brochure because such information would not be understood by the average person and would be of little use to the consumer.

The Commissioner emphasizes that the User Instructional Brochure is intended not only for the hearing aid user but also for the physician, audiologist, and dispenser—it is useful to these person when fitting the hearing-impaired person with a hearing aid, when evaluating the appropriateness of an aid with which the user has been fitted, and when repairing the hearing aid. The Commissioner therefore rejects these comments.

16. The proposed regulation provided that the medical evaluation could not be waived if the prospective purchaser exhibited any one of seven listed conditions:

i. Visible congenital or traumatic deformity of the ear.

ii. History of active drainage from the ear within the previous 90 days.

iii. History of sudden or rapidly progressive hearing loss within the previous 90 days.

iv. Acute or chronic dizziness.

v. Unilateral hearing loss of sudden or recent onset within the previous 90 days.

vi. Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz.

vii. Visible evidence of cerumen accumulation or a foreign body in the ear canal.

Many comments questioned whether dispensers could determine the existence of these conditions. Others questioned the completeness of the list.

The final regulation requires that all prospective hearing aid users obtain a medical evaluation to determine the cause of their hearing loss before pur-

chase of a hearing aid, unless the medical evaluation is specifically waived. The regulation also requires that each prospective user be provided with a User Instructional Brochure, which emphasizes the importance of medical evaluation. Although a waiver of the medical evaluation requirement is allowed, the hearing aid dispenser is prohibited from actively encouraging the use of this waiver.

The Commissioner wishes to avoid creating the impression that a medical evaluation is needed only if the enumerated symptoms are exhibited. As a result, the Commissioner is removing these seven conditions from the waiver provision. The final regulation requires that the hearing aid dispenser advise the prospective user to consult promptly with a licensed physician (preferably a physician who specializes in diseases of the ear) if the dispenser observes any of the listed conditions in the prospective user.

The original list of seven conditions was developed by the American Council of Otolaryngology (ACO) for use as a screening procedure by hearing aid dispensers. Although hearing aid dispensers cannot diagnose the cause of hearing loss, the Commissioner agrees with the ACO that hearing aid dispensers can recognize the existence of these symtoms. The Commissioner expects that hearing aid dispensers will be conscientious in impressing the importance of a medical examination upon prospective users exhibiting any of these symptoms.

One condition, pain or discomfort of the ear, has been added to the seven listed, because such pain or discomfort would indicate a medical problem that should be diagnosed and treated.

17. Nine comments objected to the caution statement required for hearing aids with a maximum sound pressure capability greater than 132 decibels (dB). Six of these comments stated that hearing aids with lower maximum output levels can cause auditory damage. The other three comments objecting to this statement, however, said that there is not sufficient evidence to support the assumption that hearing aids with maximum sound pressure capabilities greater than 132 dB can cause auditory damage.

As stated in the preamble to the proposed regulation, this statement was based on a recommendation from the Academy of Rehabilitative Audiology (ARA). It was stated by ARA that its recommendation was based on information available on the hazardous effects of high-level industrial and environmental noise and on certain scientific articles that advise caution in fitting high-output hearing aids. The academy noted that 132 dB might eventually be determined to be too high and some lower level should be substituted but that, in the absence of such data, the statement should be included in the regulation as proposed.

To avoid unnecessarily alarming persons who have reservations about hearing aids, the Commissioner feels that this statement should be required only for hearing aids whose maximum sound pressure capability exceeds 132 dB. The Commissioner expects that hearing health professionals will take the possible side effects from a high-output aid into consideration in selecting and fitting a hearing aid. Under the final regulation, this statement is required to be included in the warning statement entitled "Warning to Hearing Aid Dispensers."

18. Seven comments objected to the requirement that the entire text of proposed § 801.421, Hearing aid devices; conditions for sale be included in the User Instructional Brochure. These comments said that this section is long and cumbersome, would be difficult for the average consumer to understand, and certain passages of it, such as those about recordkeeping, are of little interest to the consumer.

The Commissioner is revising the final regulation so that the User Instructional Brochure include a summary of the requirements of § 801.421. This summary is now contained in the notice entitled "Important Notice for Prospective Hearing Aid Users." The Commissioner agrees that it is not necessary to require that the entire text of the regulation be included because the required summary will be more easily understood by hearing-impaired consumers.

19. Four comments suggested that the word "caution" be deleted from the "caution statements" required to be included in the User Instructional Brochure, because the word "caution" implied a danger that did not exist and would be unnecessarily alarming to some consumers. Eight comments objected to the required caution statement with reference to the sale of hearing aids being restricted by Federal regulation, because this tended to place hearing aids in the category of prescription devices, which they said is inappropriate. Two comments objected to the inclusion of the caution statement with respect to a hearing aid not restoring normal hearing and not preventing or improving the cause of the hearing loss. These comments said that this might be interpreted as implying that hearing aids will not improve hearing.

The final regulation is revised to require that the substance of three of the four caution statements in the proposed regulation be included in one section of the User Instructional Brochure under the heading, "Important Notice for Prospective Hearing Aid Users." The other caution statement concerning hearing aids with a maximum sound pressure capability greater than 132 dB is included in the User Instructional Brochure in the section entitled "Warning to Hearing Aid Dispensers."

The word "caution" is deleted from the "Important Notice for Prospective Hearing Aid Users" because the Commissioner believes that the use of such a word is not essential to the communication of necessary hearing aid health information and might unnecessarily frighten those consumers who have a negative attitude toward the use of a hearing aid.

The "Important Notice for Prospective Hearing Aid Users" does point out that Federal law restricts the sale of hearing aids. Upon the effective date of the regulation, hearing aids will become restricted devices under section 520(e) of the Federal Food, Drug, and Cosmetic Act. The Commissioner believes that it is necessary to alert hearing aid consumers and dispensers to this fact so that they are aware of the restrictions that apply to the sale of a hearing aid.

The Commissioner believes that the statement in the proposal that hearing aids do not restore normal hearing and do not prevent or improve hearing loss is necessary to protect prospective hearing aid users from misleading claims about the benefits to be expected from a hearing aid and, accordingly, is retaining the requirement that this statement appear in the User Instructional Brochure. Some promotional material for hearing aids, in the past, has been worded to imply that the hearing aid would restore normal hearing or would prevent or improve the organic conditions causing hearing loss.

Several comments suggested that a child with a hearing loss should be directed to an audiologist because of the importance of hearing habilitation to speech and language development, and the educational and social growth of the child.

The Commissioner agrees with these comments and is including such a statement in the "Important Notice for Prospective Hearing Aid Users".

20. Three comments objected to the fact that technical data, required to be provided in the User Instructional Brochure, would have to be measured in accordance with the test procedures of the Acoustical Society of America, Standard for Specification of Hearing Aid Characteristics, ASA STD 7–1976 (previously ANSI S 3.22–1976). These comments generally pointed out that it was inappropriate for the Commissioner to establish such a test-reference requirement. One of these comments also argued that it would be necessary for the Commissioner to follow the procedures of section 514 of the Medical Device Amendments of 1976 to establish performance standards.

It should be emphasized that the proposed regulation did not establish, nor did it contain, performance standards for hearing aids. The regulation would merely describe the test reference methods to be used to determine the technical data values that must be included in hearing aid labeling and would not prescribe any minimum or maximum performance levels or product design requirements. The purpose of the test reference method requirement is to simplify comparing the performance of various hearing aids and measuring the performance of a particular hearing aid to determine if it is performing within labeled specifications and thus to ensure that the labeling is accurate and not false or misleading. The Commissioner believes that the technical data requirement is needed and is authorized by section 701(a) of

[illegible] Food, Drug, and Cosmetic Act [illegible] effective enforcement of section [illegible] of the act, and that the labeling requirement is meaningless without a [illegible] test procedure to develop the required information.

21. Seven comments suggested that the term "useful gain" has no scientific meaning, was not used by the Acoustical Society of America, and should not be used in the regulation. These comments suggested that the term "Reference test gain" alone be used.

The Commissioner agrees with these comments and the change is made accordingly.

22. Four comments suggested that for clarity, the regulation should indicate that induction coil sensitivity is required only for aids with telephone coils. Further, five comments suggested that "input-output curve" and "attack and release times" are required only for hearing aids with automatic gain control.

The Commissioner agrees with all these comments and these changes are made accordingly.

23. One comment objected to the prohibition against including in the User Instructional Brochure any statement prohibited by FTC regulations. It asserted that the requirement is inappropriate as a matter of law because FDA regulations are enforceable by criminal penalties while FTC regulations are enforceable only by civil penalties, and if Congress had intended FTC regulations to be enforceable by criminal penalties, it would have so stated in the legislation governing that agency.

This statement (the prohibition) is not intended to incorporate by reference FTC regulations. The statement is intended to indicate that the requirement does not prevent FTC from enforcing its regulations. If a statement in the User Instructional Brochure violates FTC regulations but does not violate FDA regulations or otherwise constitute misbranding under section 502 of the act, the case will be referred to FTC for enforcement. It should be noted that certain statements that are prohibited by FTC regulations may also constitute misbranding under section 502 of the act and may thus be subject to action by either agency.

24. Two hundred and twenty-three comments supported the general requirement that a hearing aid shall not be sold unless the prospective user has been examined by a physician who has determined that the patient may be considered a candidate for a hearing aid. One hundred comments opposed this requirement.

Those comments supporting the general requirement generally stated that it is necessary that a physician examine a patient to determine the cause of the hearing loss and whether conditions causing the hearing loss are medically correctable. They also pointed out that a physician alone is trained to make such a diagnosis and that, if a hearing aid is purchased and a medically correctable condition goes undiagnosed and untreated, it could cause serious health problems for the hearing aid user.

Those opposing the general medical evaluation requirement generally argued that consumers should not be forced to see a physician if they do not want to, that the requirement would add an unnecessary cost to the already high cost of a hearing aid, and that physicians are not generally aware of the capabilities of hearing aids, even when such use is appropriate.

The Commissioner has determined that it is very important that all medically treatable conditions that may affect hearing be identified and treated before the hearing aid is purchased. The physician is the only person who is qualified to make a medical diagnosis and prescribe treatment. Some persons with remediable ear disease do not receive medical attention and rely solely on a hearing aid until the disease is no longer remediable. One purpose of the medical evaluation requirement is to prevent treatable conditions from going undiagnosed and untreated.

The general medical evaluation requirement is not expected to add considerably to the cost of a hearing aid. The Commissioner is aware of dispensing practices where the fee paid to the physician will be saved in the form of a lower fee paid to the hearing aid dispenser for the hearing aid. Further, many consumers will be saved the expense of an unnecessary purchase of a hearing aid.

The argument of people who feel that they should not be forced to undergo a medical evaluation is discussed below in the section dealing with the waiver of the medical evaluation requirement.

For these reasons, the Commissioner has determined that medical evaluation should generally be required before the purchase of a hearing aid.

25. Twenty-seven comments suggested that a medical evaluation should only be required for the first purchase of a hearing aid, because once the medical evaluation has been made, no conditions could arise that would make medical evaluation necessary in the future.

The Commissioner rejects these comments. The period between purchases could be 3 years or more. Many conditions causing further hearing loss could arise during such a period, and such conditions would warrant medical evaluation.

26. Forty-eight comments addressed the requirement that the medical evaluation occur 6 months before the purchase of the hearing aid. Twenty-one of these comments stated that the period should be less than 6 months. Most of these comments suggested a period of 3 months or less. The comments were generally based on the argument that too many changes could occur in a 6-month period and that these changes would negate a previous medical clearance. Ten comments said that 6 months was an appropriate period. Seventeen comments said that the period should be more than 6 months. Most of these comments suggested a period of 12 to 24 months. These comments generally argued that many people were slow to purchase a hearing aid and that the medical evaluation, once made, would be sufficient.

The Commissioner has determined that medical evaluation should be made no more than 6 months before the purchase of the hearing aid. This period is sufficiently long to give the purchaser time to shop around for a proper hearing aid, and it is sufficiently short to decrease the likelihood of substantial changes in the prospective user's medical condition.

27. Eight comments said that the parent or guardian of a prospective hearing aid user under the age of 18 should be permitted to waive the medical evaluation requirement for the child because parents should be free to determine what is in the best interest of their children.

Seventeen opposing comments specifically said that under no circumstances should a prospective hearing aid user under the age of 18 or the parent or guardian of such a person be permitted to obtain a hearing aid without a medical evaluation of the hearing loss because proper hearing is vital to the educational and social development of people in that age group.

The Commissioner has determined that, for those under the age of 18, there is a special concern that medical conditions that led to hearing impairment be identified, diagnosed, and treated by a physician. In addition to the risk to a child's health because of undiagnosed and untreated conditions, there is concern that a child's untreated, or inadequately treated, hearing impairment may interfere with the development of speech and language, learning, and normal adaptation to society. Accordingly, the final regulation does not allow a waiver of the medical evaluation requirement for anyone under the age of 18.

28. Three comments suggested that a physician may be unwilling to sign the required statement saying that he has found "no medical reasons why the individual should not be fitted with a hearing aid."

The Commissioner agrees that many physicians may be unwilling to sign such a statement. Such a statement is not necessary for the purposes of this regulation. The wording is therefore changed to reflect that the patient has been examined and that the physician has determined that the patient is a candidate for a hearing aid. This language was suggested in the comment of the American Council of Otolaryngology.

29. Thirty comments specifically said that a waiver of the medical evaluation requirement should be allowed. Sixty-one comments specifically said that such a waiver should not be allowed.

Comments supporting the waiver generally said that such a provision was necessary to protect the freedom of those who had strong feelings against being examined by a physician, especially those who had religious beliefs that forbade them from being treated by a physician. Many also pointed out that elderly peo-

ple in rural areas would be heavily burdened by the medical evaluation requirement if a waiver were not allowed. Those who opposed the waiver, on the other hand, generally argued that medical evaluation is an absolute necessity because serious health problems could arise if a medical evaluation is waived and a correctable condition causing the hearing loss goes untreated.

Although the Commissioner strongly recommends that all prospective hearing aid users obtain a medical evaluation of a hearing loss before purchasing a hearing aid, he recognizes that a waiver should be allowed for those who have religious or personal beliefs against a medical evaluation and for the rare circumstance where an individual would have great difficulty in obtaining a medical evaluation due to the lack of a physician in the area. Accordingly, the final regulation permits a prospective hearing aid user over the age of 18 to waive the medical evaluation requirements.

30. Four comments objected to the statement in proposed § 801.421(a)(4) that State and local governments may impose more stringent conditions for sale than are imposed by the FDA regulation. These comments pointed out that section 521 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360k), which was added by the Medical Device Amendments of 1976, provides that State and local laws that are inconsistent with or in addition to the regulation are preempted.

Specifically section 521(a) of the act provides that no State or local government may establish or continue in effect any requirement with respect to the safety and effectiveness of a device or to any other requirement applicable to the device under the act, if such requirement is different from, or in addition to, requirements which are applicable to the specific device under the act. Section 521(b) provides that the Commissioner may upon application of a State or local government exempt a requirement from the preemption of section 521(a) if the State or local requirement for the device is more stringent than requirements for the device imposed by FDA under the act, or if the requirement is necessitated by compelling local conditions and compliance with the State or local requirement would not cause the device to be in violation of a requirement under the act.

Section 521 of the act applies to specific State and local requirements with respect to the safety and effectiveness of hearing aids. The section does not, however, preempt State and local laws with respect to the licensing of hearing aid dispensers, audiologists, or physicians. In the Commissioner's view, such laws do not constitute "requirements with respect to a device" within the meaning of section 521 of the act. Moreover, another provision of the Medical Device Amendments, section 520(e) (21 U.S.C. 360j(e)), explicitly recognizes the continued viability of State licensing laws to prescribe the practitioners qualified to administer or use devices.

Therefore, because State and local governments will be required to petition for exemptions from section 521(a) of the act for differing requirements concerning hearing aid labeling or conditions on the sale of hearing aids, the Commissioner has determined that the statement in the proposed regulation is inappropriate, and it is deleted from the final regulation. A proposed regulation governing the procedures pursuant to which State and local governments may petition for exemption from section 521(a) of the act will be published in the FEDERAL REGISTER in the near future.

The Commissioner has also determined that the preemption provision of section 521(a) of the act does not apply to rules or requirements established by Federal, State, or local agencies to control the expenditure of public funds for purchasing hearing aids and hearing health care services for the hearing impaired, i.e., third-party payment programs. Such requirements often establish standards for the screening and diagnosis of individuals who will receive hearing aids through publicly funded programs. These standards are to assure the proper use of public funds. It is the Commissioner's view that such rules and requirements for the expenditure of public funds for hearing aids are payment criteria established by the payer or purchaser and do not represent "requirements with respect to a device" within the meaning of section 521(a) of the act.

31. Four comments objected to the requirement that the dispenser read and explain to the prospective user the four caution statements imposed by § 801.420 (c)(2). These comments said this requirement is impractical and unnecessary and is an unwarranted interference in the hearing aid dispenser's business.

The Commissioner believes that this requirement is necessary to assure that the prospective user is informed of matters essential for the safe and effective use of a hearing aid. The burden placed on the hearing aid dispenser by this requirement is minimal. Therefore, the comments are rejected. The cautionary statements have been condensed into new sections entitled "Important Notice for Prospective Hearing Aid Users" and "Warning to Hearing Aid Dispensers". This notice for prospective hearing aid users describes, in lay language, the restrictions on the sale of hearing aids and the steps a prospective hearing aid user should follow to obtain quality hearing health care. The dispenser will be required to review this information with the prospective user before dispensing a hearing aid.

32. Four comments objected to the requirement that manufacturers and distributors provide, upon request, sufficient copies of the User Instructional Brochure for distribution to users or prospective users of hearing aids. These comments generally pointed out that this requirement was too broad, that too many people would request copies, and that it should be limited to those who have already decided to purchase a particular hearing aid.

The Commissioner believes that the User Instructional Brochure should be readily available to those who are shopping for a hearing aid and that such persons should be aware of the information contained in the User Instructional Brochure. The Commissioner also believes that any problems of persons requesting brochures for no reason will be minimal and will not significantly increase the cost of producing the brochure. Accordingly, this requirement is not changed in the final regulation.

33. Four comments objected to the requirement that the hearing aid dispenser retain for 3 years a copy of the physician's statement or the patient's waiver. Two of these comments said the period should be 5 years—the average life of a hearing aid. The other two comments said 1 year was sufficient because any problems would show up within 1 year.

The Commissioner is retaining the 3-year period for maintaining such records. Any problems resulting from the failure of the hearing aid dispenser to inform the user of the necessity of a medical evaluation would likely occur during the 3-year period after the sale.

34. Two comments suggested that it be clarified that mail order sales are not prohibited by the regulation.

The Commissioner is not aware of any abuses in mail order sales of hearing aids, and several users have indicated their satisfaction with hearing aids bought through the mail. The Commissioner has determined not to prohibit mail order sales provided that all the requirements of the regulation have been met. No statement in the regulation to this effect is necessary.

REVIEW OF LABELING

In the preamble to the proposed regulation, the Commissioner stated that the final regulation would be accompanied by a notice published in the same issue of the FEDERAL REGISTER and that the notice would require submission of copies of the proposed User Instructional Brochure and all other labeling for hearing aids no later than 60 days before the effective date of the final regulation.

At the time of the proposal, the legal authority for requiring such information was section 704 of the act (21 U.S.C. 374) relating to factory inspection. Section 704 authorizes FDA to enter at reasonable times and in a reasonable manner, establishments where devices are manufactured or held for sale and to inspect such establishments and related equipment and materials and specifically to inspect device labeling. It is the Commissioner's opinion that section 704 of the act, in authorizing on-site inspections of device labeling, also authorizes the Commissioner to require the submission of such labeling to FDA.

With the enactment of the Medical Device Amendments, additional authority was provided to FDA to require the submission of device labeling. Newly enacted section 519 of the act (21 U.S.C.

...Records and Reports on Devices, specifically authorizes FDA, within certain limits, to prescribe regulations to require device manufacturers to submit device labeling to FDA.

Accordingly, based on the authority provided to FDA by sections 519 and 704 of the act, the Commissioner has decided to require manufacturers of hearing aids that were in commercial distribution of the effective date of the regulation—August 15, 1977—to submit to FDA copies of the User Instructional Brochure and all other labeling for hearing aids. The Commissioner has also decided that this requirement should be included in the body of the final hearing aid labeling regulation, rather than as a separate notice as indicated in the proposal, to satisfy the requirements of section 519 of the act that a "regulation" be issued to require such submissions.

The Commissioner has determined that the submission of such labeling is necessary to ensure conformance with the requirements of § 801.420 and to determine whether such devices are adulterated or misbranded, or otherwise in violation of the act. The Commissioner has also determined that this requirement is not "unduly burdensome" within the meaning of section 519 of the act since such labeling is generally prepared by the manufacturer or distributor in the normal course of business.

The Commissioner also notes that the labeling for devices newly marketed subsequent to August 15, 1977 will be reviewed by FDA in accordance with the procedures of section 510(k) of the act (21 U.S.C. 360(k)) (premarket review); section 513(f)(2) of the act (21 U.S.C. 360c(f)(2)) (reclassification); or section 515 of the act (21 U.S.C. 360e) (premarket approval) of the act, as applicable.

Two comments on this portion of the proposal suggested that it would be difficult to comply with the labeling submissions requirement within the 120-day period allowed by the preamble to the proposed regulation. Accordingly, to allow more time to comply, § 801.420(d) requires that the manufacturer of a hearing aid submit to FDA a copy of the User Instructional Brochure and all other labels and labeling for the hearing aid on or before the effective date of the regulation—August 15, 1977—for those hearing aids in commercial distribution at that time.

Background data and information on which the Commissioner relies in promulgating this regulation have been placed on file for public review in the office of the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857. The following is a list of these documents:

1. "Paying Through the Ear: A Report on Hearing Health Care Problems," Public Citizen's Retired Professional Action Group, 1973.

2. "Hearing Aids and the Older American," Hearings before the Subcommittee on Consumer Interests of the Elderly of the Special Committee on Aging, United States Senate, 93d Cong. 1st sess., Parts 1 and 2, Washington, DC, September 10, 1973.

3. Memorandum on the HEW Intradepartmental Task Force on Hearing Aids, including minutes of the HEW Intradepartmental Task Force Meetings and agency comments on the Task Force reports.

4. "Final Report to the Secretary on Hearing Aid Health Care," prepared by the Department of Health, Education, and Welfare Intradepartmental Task Force on Hearing Aids, July 1975. The report contains the following appendices:

Appendix A—Preliminary Report on Hearing Aid Health Care, September 1974.

Appendix B—Supplementary Report on Hearing Aid Health Care, October 1974.

Appendix C—Synopsis of written comments on the Preliminary and Supplementary Task Force Reports.

Appendix D—Transcript of public hearings on the Preliminary and Supplementary Task Force Reports.

Appendix E—Hearing Aid Specialists Act.

5. "1971 Health Survey Report," National Center for Health Statistics, Health Resources Administration, Public Health Service, Department of Health, Education, and Welfare.

6. "A Partnership in Better Hearing," a paper submitted by the Hearing Aid Industry Conference to the HEW Intradepartmental Task Force on Hearing Aids, August 13, 1974.

7. Minneapolis Study—Congressional Record—Senate, July 18, 1974, S12850. New York City Study—Congressional Record—Senate, July 11, 1974, S10300 through S10304. Baltimore Study—RPAG Report, "Paying Through the Ear—A Report on Hearing Health Care Problems," Private Citizens, Inc., 1972, Chapter I, p. 5. Detroit Study—Congressional Record—Senate, July 18, 1974, S12851 through S12854.

8. "The Hearing Aid Industry, A Survey of the Hard of Hearing," a report to the National Hearing Aid Society and the Hearing Aid Industry Conference, prepared by Market Facts, Inc., April 1971.

9. "1974 FDA Report on Hearing Aid Label Review."

10. S 3.22, 1976 American National Standard for Specification of Hearing Aid Characteristics.

11. S 3.3, 1960 (R. 1971) American National Standard Methods for Measurement of Electroacoustical Characteristic of Hearing Aids.

12. S 3.8, 1967 (R. 1971) American National Standard Method of Expressing Hearing Aid Performance.

13. "Staff Study of the State Licensing Laws and Training Requirements for Hearing Aid Dealers," Permanent Subcommittee on Investigations of the Senate Committee on Government Operations, 94th Cong., 1st Sess., October 1975.

14. "Problems of the Hearing Aid Industry." Hearings before the Subcommittee on Government Regulation of the Select Committee on Small Business, United States Senate, 94th Cong., 1st Sess., on Economic Problems in the Hearing Aid Industry, Washington, DC, May 20, 21, and 22, 1975.

15. Hearings before the Senate Permanent Subcommittee on Investigations, United States Senate, 95th Cong., 1st Sess., Hearings on the Hearing Aid Industry, Washington, DC, April 1 and 2, 1976.

16. Acoustical Society of America Standard, Specification of Hearing Aid Characteristics, ASA STD 7-1976 (ANSI S 3.22-1976), published by the American Institute of Physics for the Acoustical Society of America, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201 (h), (k), (m), (n), 502, 519, 520(e), 701(a), 704, 52 Stat. 1040–1041, as amended 1050–1051 as amended, 1055, 67 Stat. 477 as amended, 90 Stat. 564–565, 567 (21 U.S.C. 321(h), (k), (m), (n), 352, 360i, 360j(e), 371(a), 374)) and under authority delegated to the Commissioner (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), Part 801 is amended as Subpart H by adding new §§ 801.420 and 801.421, to read as follows:

§ 801.420 Hearing aid devices; professional and patient labeling.

(a) *Definitions for the purposes of this section and § 801.421.* (1) "Hearing aid" means any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing.

(2) "Ear specialist" means any licensed physician who specializes in diseases of the ear and is medically trained to identify the symptoms of deafness in the context of the total health of the patient, and is qualified by special training to diagnose and treat hearing loss. Such physicians are also known as otolaryngologists, otologists, and otorhinolaryngologists.

(3) "Dispenser" means any person, partnership, corporation, or association engaged in the sale, lease, or rental of hearing aids to any member of the consuming public or any employee, agent, sales person, and/or representative of such a person, partnership, corporation, or association.

(4) "Audiologist" means any person qualified by training and experience to specialize in the evaluation and rehabilitation of individuals whose communication disorders center in whole or in part in the hearing function. In some states audiologists must satisfy specific requirements for licensure.

(5) "Sale" or "purchase" includes any lease or rental of a hearing aid to a member of the consuming public who is a user or prospective user of a hearing aid.

(6) "Used hearing aid" means any hearing aid that has been worn for any period of time by a user. However, a hearing aid shall not be considered "used" merely because it has been worn by a prospective user as a part of a bona fide hearing aid evaluation conducted to determine whether to select that particular hearing aid for that prospective user, if such evaluation has been conducted in the presence of the dispenser or a hearing aid health professional selected by the dispenser to assist the buyer in making such a determination.

(b) *Label requirements for hearing aids.* Hearing aids shall be clearly and permanently marked with:

(1) The name of the manuacturer or distributor, the model name or number, the serial number, and the year of manufacture.

(2) A "+" symbol to indicate the positive connection for battery insertion, unless it is physically impossible to insert the battery in the reversed position.

(c) *Labeling requirements for hearing aids*—(1) *General.* All labeling information required by this paragraph shall be included in a User Instructional Brochure that shall be developed by the manufacturer or distributor, shall ac-

company the hearing aid, and shall be provided to the prospective user by the dispenser of the hearing aid in accordance with § 801.421(c). The User Instructional Brochure accompanying each hearing aid shall contain the following information and instructions for use, to the extent applicable to the particular requirements and characteristics of the hearing aid:

(i) An illustration(s) of the hearing aid, indicating operating controls, user adjustments, and battery compartment.

(ii) Information on the function of all controls intended for user adjustment.

(iii) A description of any accessory that may accompany the hearing aid, e.g., accessories for use with a television or telephone.

(iv) Specific instructions for:

(*a*) Use of the hearing aid.

(*b*) Maintenance and care of the hearing aid, including the procedure to follow in washing the earmold, when replacing tubing on those hearing aids that use tubing, and in storing the hearing aid when it will not be used for an extended period of time.

(*c*) Replacing or recharging the batteries, including a generic designation of replacement batteries.

(v) Information on how and where to obtain repair service, including at least one specific address where the user can go, or send the hearing aid to, to obtain such repair service.

(vi) A description of commonly occurring avoidable conditions that could adversely affect or damage the hearing aid, such as dropping, immersing, or exposing the hearing aid to excessive heat.

(vii) Identification of any known side effects associated with the use of a hearing aid that may warrant consultation with a physician, e.g., skin irritation and accelerated accumulation of cerumen (ear wax).

(viii) A statement that a hearing aid will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions.

(ix) A statement that in most cases infrequent use of a hearing aid does not permit a user to attain full benefit from it.

(x) A statement that the use of a hearing aid is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lipreading.

(xi) The warning statement required by paragraph (c) (2) of this section.

(xii) The notice for prospective hearing aid users required by paragraph (c) (3) of this section.

(xiii) The technical data required by paragraph (c) (4) of this section, unless such data is provided in separate labeling accompanying the device.

(2) *Warning statement.* The User Instructional Brochure shall contain the following warning statement:

WARNING TO HEARING AID DISPENSERS

A hearing aid dispenser should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid if the hearing aid dispenser determines through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following conditions:

(i) Visible congenital or traumatic deformity of the ear.

(ii) History of active drainage from the ear within the previous 90 days.

(iii) History of sudden or rapidly progressive hearing loss within the previous 90 days.

(iv) Acute or chronic dizziness.

(v) Unilateral hearing loss of sudden or recent onset with the previous 90 days.

(vi) Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz.

(vii) Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.

(viii) Pain or discomfort in the ear.

Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels because there may be risk of impairing the remaining hearing of the hearing aid user. (This provision is required only for those hearing aids with a maximum sound pressure capability greater than 132 decibels (dB).)

(3) *Notice for prospective hearing aid users.* The User Instructional Brochure shall contain the following notice:

IMPORTANT NOTICE FOR PROSPECTIVE HEARING AID USERS

Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.

Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing aid. The physician will refer you to an audiologist or a hearing aid dispenser, as appropriate, for a hearing aid evaluation.

The audiologist or hearing aid dispenser will conduct a hearing aid evaluation to assess your ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist or dispenser to select and fit a hearing aid to your individual needs.

If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial-rental or purchase-option program. Many hearing aid dispensers now offer programs that permit you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid.

Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.

CHILDREN WITH HEARING LOSS

In addition to seeing a physician for a medical evaluation, a child with a hearing loss should be directed to an audiologist for evaluation and rehabilitation since hearing loss may cause problems in language development and the educational and social growth of a child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with a hearing loss.

(4) *Technical data.* Technical data useful in selecting, fitting, and checking the performance of a hearing aid shall be provided in the User Instructional Brochure or in separate labeling that accompanies the device. The determination of technical data values for the hearing aid labeling shall be conducted in accordance with the test procedures of the Acoustical Society of America Standard for Specification of Hearing Aid Characteristics, ASA STD 7-1976.[1] As a minimum, the User Instructional Brochure or such other labeling shall include the appropriate values or information for the following technical data elements as these elements are defined or used in such standard:

(i) Saturation output curve (SSPL 90 curve).

(ii) Frequency response curve.

(iii) Average saturation output (HF-Average SSPL 90).

(iv) Average full-on gain (HF-Average full-on gain).

(v) Reference test gain.

(vi) Frequency range.

(vii) Total harmonic distortion.

(viii) Equivalent input noise.

(ix) Battery current drain.

(x) Induction coil sensitivity (telephone coil aids only).

(xi) Input-output curve (ACG aids only).

(xii) Attack and release times (ACG aids only).

(5) *Statement if hearing aid is used or rebuilt.* If a hearing aid has been used or rebuilt, this fact shall be declared on the container in which the hearing aid is packaged and on a tag that is physically attached to such hearing aid. Such fact may also be stated in the User Instructional Brochure.

(6) *Statements in User Instructional Brochure other than those required.* A User Instructional Brochure may contain statements or illustrations in addition to those required by paragraph (c) of this section if the additional statements:

(i) Are not false or misleading in any particular, e.g., diminishing the impact of the required statements; and

(ii) Are not prohibited by this chapter or by regulations of the Federal Trade Commission.

(d) *Submission of all labeling for each type of hearing aid.* Any manufacturer of a hearing aid described in paragraph (a) of this section shall submit to the Food and Drug Administration, Bureau of Medical Devices and Diagnostic Products, Division of Compliance, HFK-116, 8757 Georgia Ave., Silver Spring, MD 20910, a copy of the User Instructional Brochure described in paragraph (c) of this section and all other labeling for each type of hearing aid on or before August 15, 1977.

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[1] Copies available from the Acoustical Society of America, 335 E. 45th St., New York, N.Y. 10017.

§ 801.421 Hearing aid devices; conditions for sale.

(a) *Medical evaluation requirements*—(1) *General.* Except as provided in paragraph (a)(2) of this section, a hearing aid dispenser shall not sell a hearing aid unless the prospective user has presented to the hearing aid dispenser a written statement signed by a licensed physician that states that the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid. The medical evaluation must have taken place within the preceding 6 months.

(2) *Waiver to the medical evaluation requirements.* If the prospective hearing aid user is 18 years of age or older, the hearing aid dispenser may afford the prospective user an opportunity to waive the medical evaluation requirement of paragraph (a)(1) of this section provided that the hearing aid dispenser:

(i) Informs the prospective user that the exercise of the waiver is not in the user's best health interest;

(ii) Does not in any way actively encourage the prospective user to waive such a medical evaluation; and

(iii) Affords the prospective user the opportunity to sign the following statement:

I have been advised by

(Hearing aid dispenser's name)

that the Food and Drug Administration has determined that my best health interest would be served if I had a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. I do not wish a medical evaluation before purchasing a hearing aid.

(b) *Opportunity to review User Instructional Brochure.* Before signing any statement under paragraph (a)(2)(iii) of this section and before the sale of a hearing aid to a prospective user, the hearing aid dispenser shall:

(1) Provide the prospective user a copy of the User Instructional Brochure for a hearing aid that has been, or may be selected for the prospective user;

(2) Review the content of the User Instructional Brochure with the prospective user orally, or in the predominate method of communication used during the sale;

(3) Afford the prospective user an opportunity to read the User Instructional Brochure.

(c) *Availability of User Instructional Brochure.* (1) Upon request by an individual who is considering purchase of a hearing aid, a dispenser shall, with respect to any hearing aid that he dispenses, provide a copy of the User Instructional Brochure for the hearing aid or the name and address of the manufacturer or distributor from whom a User Instructional Brochure for the hearing aid may be obtained.

(2) In addition to assuring that a User Instructional Brochure accompanies each hearing aid, a manufacturer or distributor shall with respect to any hearing aid that he manufactures or distributes:

(i) Provide sufficient copies of the User Instructional Brochure to sellers for distribution to users and prospective users;

(ii) Provide a copy of the User Instructional Brochure to any hearing aid professional, user, or prospective user who requests a copy in writing.

(d) *Recordkeeping.* The dispenser shall retain for 3 years after the dispensing of a hearing aid a copy of any written statement from a physician required under paragraph (a)(1) of this section or any written statement waiving medical evaluation required under paragraph (a)(2)(iii) of this section.

(e) *Exemption for group auditory trainers.* Group auditory trainers, defined as a group amplification system purchased by a qualified school or institution for the purpose of communicating with and educating individuals with hearing impairments, are exempt from the requirements of this section.

Effective date. This regulation shall become effective August 15, 1977.

(Secs. 201(h), (k), (m), (n), 502, 519, 520(e), 701(a), 704, 52 Stat. 1040–1041 as amended, 1050–1051 as amended, 1055, 67 Stat. 477 as amended, 90 Stat. 564–565, 567 (21 U.S.C. 321 (h), (k), (m), (n), 352, 360i, 360j(e), 371(a), 374).)

Dated: February 10, 1977.

SHERWIN GARDNER,
Acting Commissioner of Food and Drugs.

NOTE.—Incorporation by reference approved by the Director of the Office of the Federal Register on January 18, 1977, and it is on file in the FEDERAL REGISTER library.

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